IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

GAYNELL GRIER, et al., individually and on behalf of others similarly situated,	)	
Plaintiffs,	)	
and	)	
SANFORD BLOCH, MARK LEVINE, TIM JONES, and WILLIAM DUNCAN, and MARY KATHRYN DUNCAN, by their next friend, ROBERT DUNCAN,	)	Case No. 3:79-3107
	)	Judge Nixon
Plaintiffs-Intervenors,	)	
v.	)	Class Action
M.D. GOETZ, JR., Commissioner, Tennessee Department of Finance and Administration, et al.,	)	
Defendants,	)	
and	)	
TENNESSEE ASSOCIATION OF HEALTH MAINTENANCE ORGANIZATIONS, et al.,	)	
Defendants-Intervenors.	)	

MEMORANDUM

This case is pending before the Court on Defendants' Motion to Modify and/or Clarify the Consent Decree (Doc. Nos. 1086, 1087), and the responses thereto (Doc. Nos. 1106, 1111, 1141, 1148, 1236). A hearing was held between June 29, 2005 and July 19, 2005, and on July 28, 2005. Due to the time-sensitive nature of this matter, the Court issued four Orders between

July 28, 2005 and August 9, 2005 (Doc. Nos. 1246, 1248, 1256, 1261) adjudicating Defendants' Motion to Modify and/or Clarify the Consent Decree. The Court hereby explains the reasons underlying its previously issued Orders.

I. BACKGROUND

This case was filed in 1979 as a class action under 42 U.S.C. § 1983 on behalf of present and future Medicaid recipients, and alleged that Tennessee's Medicaid program violated the requirements of the Medicaid Act, 42 U.S.C. §§ 1396, et seq., and the Due Process Clause of the Fourteenth Amendment. Specifically, the original Plaintiffs asserted that Tennessee's Medicaid program failed to provide them with adequate notice and procedural protection upon denial of their claims. These issues were resolved in 1986 through a consent decree. A second consent decree also dealing with notice and hearing requirements was entered in 1992.

In January 1994, Tennessee converted its traditional Medicaid fee-for-service program to a managed care model known as TennCare. TennCare, which expanded the scope of eligibility beyond Tennessee's previous Medicaid program, is a special demonstration project authorized by the United States Secretary of Health and Human Services (the "Secretary") pursuant to the waiver authority conferred by section 1115 of the Social Security Act, 42 U.S.C. § 1315. Instead of directly purchasing medical services for eligible individuals, TennCare contracts with private managed care contractors ("MCCs")[1] to provide healthcare to TennCare recipients. From

[1] The State contracts with three types of MCCs. Managed care organizations ("MCO") administer medical benefits. Behavioral health organizations ("BHO") administer mental health and addiction treatment. Pharmacy benefits managers ("PBM") administer prescription drug benefits. All three types of organizations maintain networks of health care providers as subcontractors to treat TennCare beneficiaries. Health care providers, in turn, are physicians or

TennCare's inception, the MCCs were required by their contracts to comply with the rules developed by Defendants (or the "State") to implement the federal notice and hearing requirements of 42 C.F.R. § 431, Subpart E.

In 1995, Plaintiffs moved to modify the second consent decree alleging that the TennCare program was being administered in a manner inconsistent with the decree, as well as federal law. This Court agreed and held that the State's TennCare notice and hearing procedures violated the Medicaid Act and the Due Process Clause of the Fourteenth Amendment. See Daniels v. Wadley, 926 F. Supp. 1305 (M.D. Tenn. 1996). Consistent with the Court's ruling, the parties negotiated, and this Court entered, an agreed order establishing policies and procedures through which the federal Medicaid due process requirements would be implemented in the context of the new managed care program ("1996 Agreed Order").

In 1999, Plaintiffs filed another motion alleging that the State failed to comply with the 1996 Agreed Order. A settlement conference followed and culminated in this Court's approval and entry of the October 26, 1999 Revised Consent Decree Governing TennCare Appeals. Shortly thereafter, six TennCare managed care organizations and their trade association, the Tennessee Association of Health Maintenance Organizations, as well as trade associations representing hospitals and pharmacists, successfully moved to intervene in order to challenge this latest decree. Subsequently, on July 31, 2000, the Court entered a Revised Consent Decree to clarify terms and correct technical errors, which became effective immediately ("2000 Consent Decree").

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other types of health care providers who are eligible by professional qualifications to participate in TennCare, and who act within their scope of practice. (See Doc. No. 908 ¶ 9, at 5.)

The intervenors challenged the 2000 Consent Decree in an appeal to the Sixth Circuit. Although the Sixth Circuit remanded the case for a fairness hearing in order to determine whether the 2000 Consent Decree was adequate, reasonable and fair to the intervenors, the Sixth Circuit rejected the intervenors other challenges to the 2000 Consent Decree. See Tenn. Ass'n of Health Maint. Orgs. ("TAHMO") v. Grier, 262 F.3d 559 (6th Cir. 2001). After a fairness hearing was held in late 2002, the State filed a motion to modify the 2000 Consent Decree. On February 14, 2003, the Court approved the 2000 Consent Decree in its entirety, but held the State's motion to modify in abeyance while a Magistrate Judge oversaw discovery and negotiations for possible modifications to the 2000 Consent Decree.

In March 2003, Governor Philip N. Bredesen's administration entered negotiations to modify the 2000 Consent Decree, and to discuss three other class actions involving different aspects of TennCare's administration. In August 2003, after six months of negotiations, the parties to the four class actions entered into a global settlement. On October 1, 2003, following a fairness hearing, the Court approved and entered the Revised Consent Decree (Modified) ("2003 Consent Decree," "Consent Decree" or "Decree").

On June 15, 2005, the State filed its present motion to modify and/or clarify the 2003 Consent Decree. The State's motion contains twenty separate requests for modification and/or clarification of the 2003 Consent Decree, a number of which contain several distinct subparts. Altogether, the motion contains thirty-four separate requests for modification and/or clarification relating primarily to prescription drugs, benefit limits, and the TennCare appeals process. For the reasons discussed below, the Court has granted in part and denied in part the State's Motion to Modify and/or Clarify the 2003 Consent Decree. (See Doc. Nos. 1256, 1261.)

II. ANALYSIS

A. LEGAL STANDARD FOR MODIFICATION OF CONSENT DECREES: THE TWO-STEP RUFO FRAMEWORK

A consent decree is an agreement between the parties that is enforceable and subject to the rules applicable to other judgments. Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367, 378 (1992). Accordingly, consent decrees are subject to modification pursuant to Federal Rule of Civil Procedure 60(b), which provides in relevant part:

> On motion and upon such terms as are just, the court may relieve a party . . . from a final judgment, order, or proceeding for the following reasons: . . . (5) . . . it is no longer equitable that the judgment should have prospective application; or (6) any other reason justifying relief from the operation of the judgment . . . .

The Supreme Court has noted that because consent decrees often remain in place for extended periods of time, a court may, pursuant to Rule 60(b)(5) of the Federal Rules of Civil Procedure, use its equitable powers to modify consent decrees to address significant changes in circumstances that have occurred during the life of a decree. Rufo, 502 U.S. at 380-81; see also Heath v. De Courcy, 888 F.2d 1105, 1109 (6th Cir. 1989) (advocating broader judicial discretion to modify consent decrees "so that the agreed upon solution to the problem giving rise to the litigation may be fine-tuned to accomplish its goal."); N.Y. State Ass'n for Retarded Children, Inc. v. Carey, 706 F.2d 956, 969 (2d Cir. 1983) (recognizing the need to adapt consent decrees "when unforeseen obstacles present themselves, to improvement when a better understanding of the problem emerges, and to accommodation of a wider constellation of interests than is represented in the adversarial courtroom."). Even if there is no significant change in circumstances, public interest also supports modification of consent decrees because such decrees "'reach beyond the parties involved directly in the suit and impact on the public's right

to

the sound and efficient operation of its institutions.'" Rufo, 502 U.S. at 381 (quoting Heath, 888 F.2d at 1109).

1. Step 1: Significant Change In Circumstances

The Supreme Court has instructed district courts to "exercise flexibility in considering requests for modification of an institutional reform consent decree . . . ." Rufo, 502 U.S. at 383. Notwithstanding this flexible approach, modification will not be warranted in all circumstances. Id. Equity is the key, and "a party may obtain relief from a court order when 'it is no longer equitable that the judgment should have prospective application,' not when it is no longer convenient to live with the terms of a consent decree." Id. (citing Fed. R. Civ. Proc. 60(b)(5)). Thus, modification of a consent decree is appropriate when the party seeking modification meets its initial burden of establishing a significant change in factual or legal circumstances, which cause the consent decree to be "onerous," "unworkable," or "detrimental to the public interest." Id. at 383-85; see also Vanguard of Cleveland v. City of Cleveland, 23 F.3d 1013, 1018-19 (6th Cir. 1994) (approving modification to fine-tune decree in order to further purpose of decree). This initial burden is heightened if the changed circumstances were anticipated at the time the decree was entered and, notwithstanding the knowledge that performance of the decree would be more onerous under the changing conditions, the moving party agreed to the decree. Id. at 385. Under this heightened standard, the movant must show that it agreed to the decree in good faith, and made a reasonable effort to comply with the decree before it may be modified. Id.

2. Step 2: Are The Proposed Modifications Suitably Tailored To The Changed Circumstances?

Once the party seeking modification has met its initial burden of showing changed circumstances, a court must "determine whether the proposed modification is suitably tailored to the changed circumstance." Id. at 391. Accordingly:

> In evaluating a proposed modification, three matters should be clear. Of course, a modification must not create or perpetuate a constitutional violation. . . . A proposed modification should not strive to rewrite a consent decree so that it conforms to the constitutional floor. Once a court has determined that changed circumstances warrant a modification in a consent decree, the focus should be on whether the proposed modification is tailored to resolve the problems created by the change in circumstances. A court should do no more, for a consent decree is a final judgment that may be reopened only to the extent that equity requires.

Id. at 391-92.

Accordingly, the Court must first review the legality of the State's proposed modifications to the 2003 Consent Decree. In this case, the State's proposed modifications must comply with federal Medicaid requirements. Schweiker v. Gray Panthers, 453 U.S. 34, 37 (1981) (noting that states participating in the Medicaid program must comply fully with the dictates of the federal statutes and regulations thereunder). At this stage of the analysis the Court must be mindful of the Sixth Circuit's recent ruling in Rosen v. Goetz, 410 F.3d 919 (6th Cir. 2005). Rosen teaches that when analyzing whether the State's policies comply with federal law, this Court owes "substantial deference" to the Centers for Medicare and Medicaid Services ("CMS"), "the agency that authored and promulgated the regulations, [and which] has approved the State's polices as fully compliant with [such] regulations." Id. at 926-27. This deference is especially high where, as here, the subject matter of the regulations is highly technical and complex. See Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994); see also PhRMA v.

Thompson, 362 F.3d 817, 821-23 (D.C. Cir. 2004) (holding that the Secretary's approval of states' initiatives pursuant to Medicaid statutes will be upheld unless "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law."). Accordingly, where CMS has specifically approved the State's proposed modifications as compliant with the underlying federal regulations, this Court must grant "substantial deference" to CMS' approval. Rosen, 410 F.3d at 927.[2]

After considering the legality of the proposed modifications, the Court's focus turns to the suitability of the proposed modifications in light of the circumstances. Although "[f]inancial constraints may not be used to justify the creation or perpetuation of constitutional violations, . . . they are a legitimate concern of government defendants in institutional reform litigation and therefore are appropriately considered in tailoring a consent decree modification." Rufo, 502 U.S. at 392-93. Further, the principles of federalism and public interest warrant deference to local administrators who have the "'primary responsibility for elucidating, assessing, and solving' the problems of institutional reform . . . ." Id. at 392. The Supreme Court recently

[2] While the Court must grant CMS' approval substantial deference, that deference is tempered by the fact that CMS did not explicitly interpret the federal regulations at issue in its approval document. (See Def. Ex. 339.) While this Court assumes that CMS did review its own regulations before issuing its approval of the State's proposed modifications, CMS' reasoning and interpretation of its regulations has not been provided to this Court or, for that matter, to the State. In contrast, the Sixth Circuit in Rosen received far more guidance from CMS regarding the interpretation of the federal regulations at issue in that case. Specifically, CMS' approval of the State's disenrollment process, which was at issue in Rosen, is far more detailed, spanning nine single-spaced pages, whereas CMS' approval of the State's proposed modifications at issue in this case, which relate to far more topics than the disenrollment process, are significantly less detailed and span seven single-spaced pages. (Compare Def. Ex. 83 Att. E, with Def. Ex. 339 Att. F.) Notably, CMS filed an amicus curiae brief in the Rosen case explaining that Tennessee's disenrollment procedures were consistent with federal regulations. Rosen, 410 F.3d at 927. The Court does not have the luxury of CMS' analysis in this case.

reaffirmed the requirement of granting deference to local administrators in Frew ex. rel. Frew v. Hawkins, 540 U.S. 431, 442 (2004), stating:

> As public servants, the officials of the State must be presumed to have a high degree of competence in deciding how best to discharge their governmental responsibilities. A State, in the ordinary course, depends upon successor officials, both appointed and elected, to bring new insights and solutions to problems of allocating revenues and resources.

As such, while a state is afforded no deference when striving to meet its initial burden of showing changed circumstances, a district court is required to give significant weight to the views of state officials in determining whether the proposed modifications are suitably tailored to the changed circumstances. Consequently, once a court finds modification is warranted, the principles of federalism favor the state's methods of modification.

B. SIGNIFICANT CHANGE IN CIRCUMSTANCES WARRANTS MODIFICATION OF THE 2003 CONSENT DECREE

The Court finds that the changes in legal circumstances do not warrant modification of the entire 2003 Consent Decree. However, modification is warranted due to the serious fiscal crisis in the TennCare program. In addition, certain provisions of the 2003 Consent Decree are unnecessarily burdensome and contrary to the public interest, thereby requiring modification.

1. Factual Background

TennCare has always faced financial difficulties due to a variety of reasons, but the traditional generosity of the program,[3] high pharmacy and medical services utilization rates,

[3] When Tennessee converted from the traditional Medicaid program to the current managed care model known as TennCare, it considerably expanded the scope of eligibility. (See

prescription drug costs, and mismanagement have been cited as the primary causes. Aware that TennCare's precarious financial situation was systemic in nature, Governor Bredesen ran for office on a promise to save the program through reform. When Governor Bredesen's new administration took office in January 2003, it faced a budget shortfall in TennCare of between $200-300 million for fiscal year 2003. (See Rosen Tr. (3/28/05) at 50-51; [4] see also Doc. No. 897 at 2 (wherein Commissioner Goetz stated that in January 2003, the new administration determined that "the state budget for fiscal year 2002-2003 was as much as $478 million out of balance, almost all of which was due to an underestimation of spending necessary to continue the operation of the TennCare program . . . .").) This budget shortfall resulted in a 9% budget cut in almost all of the State's programs. (Id.) In light of this shortfall and the administration's campaign to reform TennCare, the State entered negotiations in March 2003 to revise the 2000 Consent Decree, and to discuss the three other class actions involving TennCare. The administration successfully obtained modifications to the 2000 Consent Decree that resulted in savings of about $150-200 million, primarily due to changes in the pharmacy provisions of the Decree. (Doc. No. 1172, Tr. at 715-16.) The severity of TennCare's fiscal crisis, however,

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Def. Ex. 83 at 1 ("TennCare's ambitious goal has been to provide coverage for individuals well beyond the requirements of Federal law.").) Prior to recent changes in the State's enrollment and eligibility policies, TennCare extended Medicaid coverage to 22.3% of its population, providing health care for more of its population than any other State in the country. (Def. Ex. 102 at 1). Thus, historically, TennCare covered one in every four and one-half citizens as compared to the national average of one in nine. (Def. Ex. 38 at 1; Def. Ex. 40 at 7; see also Def. Ex. 212 at 29.) In addition to expanding eligibility, TennCare provided comprehensive medical benefits with relatively few limits. (Def. Ex. 38 at 9-12.)

[4] "Rosen Tr." refers to testimony admitted in evidence during the trial held from March 28 to April 7, 2005 regarding the State's disenrollment and appeals procedures in the related matter of Rosen v. Goetz, No. 3:98-627 (M.D. Tenn.) (Haynes, J.).

remained unknown until late 2003, a few months after the 2003 Consent Decree was entered and approved by the Court. (Rosen Tr. (3/28/05) at 63-64.)

In mid-2003 during the negotiations of the TennCare class actions, a consortium of stakeholders[5] of TennCare retained McKinsey & Company, a consulting firm, to conduct an assessment of, and identify options to ensure, TennCare's financial viability for the next five years. In December 2003, McKinsey released the first of two reports. (See Def. Ex. 38.) The first report concluded that "even with current and planned improvement efforts and solid program management, TennCare as it is constructed today will not be financially viable." (Id. at 3.) The report predicted that, depending on the economy and other factors, TennCare's total cost could be expected to rise to $12.2 billion by fiscal year 2008, with state spending growing to $3.8 billion. (Id.) This amount represented approximately 36% of state tax revenue and consumption of 91% of new state revenue. (Id.) This report explained that the "threat to the program's financial viability, is largely the result of expected spending for pharmaceuticals, professional services, and outpatient services and of the demands placed on all parts of the program by growing enrollment." (Id. at 19.) Although identifying the four main factors that increased TennCare's costs, pharmacy costs were predicted to be the "single most significant source of future cost increases . . . , driving nearly 60 percent of total growth through fiscal year 2008 and contributing nearly $2.6 billion in total cost growth during that period." (Id. at 29.) The State was surprised by this indictment of TennCare, especially after having negotiated cost-savings provisions in the pharmacy sections of the 2003 Consent Decree. (See Rosen Tr.

[5] These stakeholders included BlueCross Blue Shield of Tennessee, Hospital Corporation of America, the Farm Bureau, twenty-two hospitals within the Tennessee Hospital Association, and Vanderbilt University. (Def. Ex. 38 at i.)

(3/28/05) at 63-64.) In February 2004, McKinsey completed its second report, identifying a variety of reform options designed to solve the long-term problems identified in the earlier report. (See Def. Ex. 39.)

Following these reports, Governor Bredesen proposed a reform package to a joint session of the House of Representatives and Senate of the State of Tennessee. See 2004 Tenn. Pub. Acts, Ch. 673, § 1. The reform package empowered the TennCare Bureau to develop and implement initiatives – subject to compliance with federal law and the federally-issued TennCare waiver – to reduce TennCare costs. Governor Bredesen's administration developed these cost-saving initiatives, which primarily dealt with benefit reductions, and submitted them for approval to CMS on September 24, 2004.

Shortly after the September submission to CMS, the State learned of two new developments that deepened TennCare's precarious financial situation. First, the State learned in early October 2004 that it would be losing approximately $140 million in federal funding for its Medicaid program. (See Rosen Tr. (3/28/05) at 89-90; Rosen Tr. (3/29/05) at 23-24.) Second, in closing out TennCare's budget for fiscal year 2004, the State learned that there had been unexpectedly high growth in pharmacy and medical utilization rates of 24% and 11%, respectively. (See Rosen Tr. (3/28/05) at 90-91; Rosen Tr. (3/29/05) at 93-96.) These growth rates exceeded even the upper range of the McKinsey estimates. (Rosen Tr. (3/29/05) at 93-96.) At this time, it became clear that the State was facing a budgetary shortfall for fiscal year 2006 of approximately $650 million in new revenue if TennCare's enrollment and benefits remained unchanged. (Rosen Tr. (3/28/05) at 102-04; Def. Ex. 27); see also Rosen v. Goetz, 410 F.3d 919, 922 (6th Cir. 2005). This shortfall was expected to exceed projections of new revenue for fiscal

year 2006, which were estimated to be approximately $465 million. (See Rosen Tr. (3/29/05) at 99; Doc. No. 1150, Tr. at 217; Def. Ex. 221.)

In an attempt to resolve the shortfall, the State pursued an even more aggressive reform initiative than the one envisioned in September 2004. Thus, the supplemental reform plan submitted to CMS for approval on February 18, 2005 sought to eliminate certain categories of non-mandatory Medicaid coverage. (See Def. Ex. 111.) As part of this plan, the State sought to disenroll approximately 323,000 of TennCare's optional beneficiaries, including those eligible for both TennCare and Medicare, those with medical conditions that make them uninsurable, the uninsureds and the Medically Needy Spend Down patients. CMS approved the State's disenrollment plan and procedures on March 24, 2005. (See Def. Ex. 83.) Plaintiffs challenged the State's disenrollment and appeals procedures in Rosen v. Goetz, No. 3:98-627 (M.D. Tenn.) (Haynes, J.), but on appeal, the Sixth Circuit upheld the State's procedures, see Rosen, 410 F.3d 919, and the State began the process of disenrolling 323,000 TennCare enrollees.[6]

Subsequently, on April 26, 2005 Defendants entered into a Memorandum of Understanding with Plaintiffs-Intervenors,[7] Defendant-Intervenors, Tennessee Hospital Association and Hospital Alliance of Tennessee, and Provider Amici, Regional Medical Center at Memphis, and a coalition of safety net providers. (Def. Ex. 225.) The Memorandum of Understanding ("MOU") requires the State to initiate a "Waiver-Based Spend Down program

[6] Unless otherwise specified, references to "enrollees," "beneficiaries," "recipients," "applicants" or "patients" include any individuals eligible for, and enrolled in, TennCare.

[7] Plaintiffs-Intervenors represent members of the Plaintiff class who face disenrollment, as opposed to the rest of the members of the Plaintiff class who remain on TennCare but face benefit reductions and other changes to their TennCare coverage.

designed to provide coverage for the [Medically Needy] who will be losing TennCare coverage under the State's TennCare reform plan." (Id.) Numerous conditions must be fulfilled prior to the implementation of this program, including successful modification of the 2003 Consent Decree, approval of the State's disenrollment procedures in Rosen v. Goetz, No. 3:98-627 (M.D. Tenn.) (Haynes, J.), approval from CMS of the State's September 24, 2004 and February 18, 2005 proposed reform plans, as well as CMS' approval of the Waiver-Based Spend Down program, and the State Legislature's appropriation of necessary funds. (Def. Ex. 225 ¶¶ 1, 3-6.) The Waiver-Based Spend Down program aims to provide coverage to Medically Needy individuals whose incomes are too high to qualify for Medicaid. (Doc. No. 1150, Tr. at 225-27.) These individuals can qualify for coverage by demonstrating that they have medical bills that bring their income down to a certain threshold. (Id.)[8]

On June 8, 2005, CMS approved some, but not all, of the State's remaining reforms relating to benefit limits and prior authorization of prescription drugs, among others. (See Def. Ex. 339.) In order for the State to implement certain of these reforms, the 2003 Consent Decree must be modified and/or clarified. In addition to the CMS-approved reforms, the State seeks other modifications to the Decree. The State contends that its proposed modifications to the 2003 Consent Decree are the key to controlling costs and operating an effective managed care system.

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[8] As this Court stated in its previously issued Memorandum Order denying Plaintiffs' Motion for Preliminary Consideration of a Fairness Hearing, "the Court shall conduct the Rufo hearing in this case expeditiously, but without regard to the MOU. If after the Court issues its ruling on the modifications to be presented at the Rufo hearing the MOU retains any relevancy . . . [the parties] may request that the Court take up the issue at that point." (Doc. No. 1075 at 2-3.) Accordingly, the Court shall not consider the MOU in determining whether the 2003 Consent Decree should be modified.

2. Change In Legal Circumstances

To begin with, the State asserts that modification is warranted due to the change in federal law through CMS' approval of the State's proposed modifications, and the passage of State legislation aimed at reforming TennCare. Similarly, the State contends that "the democratically-elected government of the State cannot be inflexibly constrained by the positions of its predecessors." (Doc. No. 1241 at 119.) The Court finds these changes do not provide sufficient basis to modify the entire 2003 Consent Decree.

i. CMS' Approval

As TennCare is a special demonstration project, the State must obtain approval from CMS to implement its reforms. Accordingly, the State submitted its proposed reforms to CMS on September 24, 2004, and again on February 18, 2005. (Def. Exs. 81, 111.) CMS responded on March 24, 2005 and June 8, 2005, approving many, but not all, of the State's reforms. (Def. Exs. 83, 339.) CMS' approval is two-fold. First, pursuant to section 1115 of the Social Security Act, 42 U.S.C. § 1315, CMS has waived compliance with some sections of the Social Security Act to permit Tennessee to implement its reforms. (See Def. Ex. 339.) Second, CMS has specifically approved and appended special terms and conditions to certain of the State's reforms. (See id., Special Terms and Conditions.) CMS' approval of the State's reforms contains CMS' implicit interpretation that these reforms comply with the sections of the Social Security Act and federal regulations that have not been waived. (See id.); see also supra p. 8 note 2.

Defendants contend that CMS' waiver/approval constitutes a change in law requiring modification of the Consent Decree. CMS' waiver of certain sections of the Social Security Act does constitute a change in law because the State is no longer required to follow federal requirements that it was previously required to follow. See System Federation No. 91 Ry. Employees' Dep't v. Wright, 364 U.S. 642, 648-51 (1961) (holding that it was an abuse of discretion not to modify the consent decree to align it with federal law because underlying federal law was amended to permit what was previously prohibited). To the extent the State's proposed modifications rely on CMS' waiver, then modification of the 2003 Consent Decree would be warranted.

That is not the case, however, and the State's reliance on System Federation is inapposite. Defendants do not rely on CMS' waiver of particular sections of the Social Security Act to demonstrate a change in law. Rather, the State contends that it "seeks leave to do no more than that which CMS . . . has permitted as consistent with the Medicaid laws . . .," and that "it has now been authoritatively determined by CMS that the underlying statute and regulations permit what the State proposes to do." (Doc. No. 1241 at 119-21) (emphasis added). CMS' interpretation that the State's proposed modifications comply with existing federal Medicaid requirements that have not been waived does not constitute a change in law because the underlying federal requirements have not changed. Unlike System Federation where the parties agreed to follow the requirements of federal law, which requirements subsequently changed, the parties in this case agreed to enact measures that went beyond minimum federal Medicaid requirements and these requirements have not changed. Authority from a federal agency to

return to the minimum requirements of federal law or to do what federal law already allows does not constitute a change in law that warrants modification of a consent decree.

Rather, CMS' interpretation of federal Medicaid regulations is akin to a Court decision interpreting or clarifying statutory law. On this point, the Supreme Court could not have been clearer:

> To hold that a clarification in the law automatically opens the door for relitigation of the merits of every affected consent decree would undermine the finality of such agreements . . . . While a decision that clarifies the law will not, in and of itself, provide a basis for modifying a decree, it could constitute a change in circumstances that would support modification if the parties had based their agreement on a misunderstanding of the governing law.

Rufo, 502 U.S. at 390 (emphasis added). The State asserts that because "CMS has also explained to the State that some of the procedures currently required by [the 2003 Consent Decree] would violate federal law, as now interpreted by CMS," the entire decree should be modified. (Doc. No. 1241 at 121) (emphasis added). The State does not contend that the entire 2003 Consent Decree is based on a misunderstanding of the governing law, but simply points to a single provision in the Decree, Paragraph C(13), which binds the State to a decision in favor of the enrollee at any stage of the appeals process. (See Doc. No. 908 ¶ C(13), at 22.) The State alleges that this provision violates federal law because a single state agency such as the TennCare Bureau must retain authority to review and overturn decisions made by hearing officers that are not officials of the single state agency. (See Def. Ex. 353.)

There has been no change in the federal law governing single state agencies; interpretation of existing law has simply been clarified by CMS in a July 6, 2005 letter to the State. (See id.) Nevertheless, this is the type of change that the Supreme Court has held could constitute a change in circumstances warranting modification because Paragraph C(13) appears

to be based on a misunderstanding of governing law. See Rufo, 502 U.S. at 390. Indeed, even if the clarification did not constitute a change in circumstances, the authority to modify a provision that violates federal law would also stem from this Court's inherent equitable powers to rectify that which is contrary to the public interest. To be clear, however, modification would be limited to Paragraph C(13) because that is the provision that violates federal law. As the other provisions of the 2003 Consent Decree are not based on a misunderstanding of governing law, CMS' recent interpretation cannot provide the justification for modifying the entire 2003 Consent Decree.

ii. Changes In State Law

Similarly, Defendants contend that changes in State law provide grounds for modifying the 2003 Consent Decree. Defendants first rely on the passage by the Tennessee Legislature of the TennCare Reform Act of 2004 to demonstrate a change in law. See 2004 Tenn. Pub. Acts, Ch. 673, § 1. Certain of the provisions of the TennCare Reform Act, however, are inapplicable to the 2003 Consent Decree. Furthermore, most of the provisions of the TennCare Reform Act become law only to the extent they are permitted under federal law. See id. As discussed, federal law has not changed, and the fact that state law now permits what federal law always permitted is inconsequential for purposes of modification of the 2003 Consent Decree. See United States v. Wayne County Mich., 95 F.App'x. 809, 815-16 (6th Cir. 2004) ("These changes in [state] law . . . do not make obligations under the consent decree 'impermissible under federal law.'" (citing Rufo, 502 U.S. at 388)).

The provision that arguably acts as a change in law affecting the 2003 Consent Decree is the State Legislature's enactment of a new definition of "medical necessity" because federal law does not define medical necessity. See Tenn. Code Ann. § 71-5-144 (2004). Yet, even the enactment of this new definition falls short of a true change in law for purposes of modification. In this case, the 2003 Consent Decree does not define medical necessity, nor is it inconsistent with the new medical necessity statute for the reasons explained in Part II.C.2.iii., infra. As the Decree does not rely on the definition of medical necessity, a change in that definition is irrelevant for purposes of modification.

Lastly, the Defendants point to the appropriations of additional funds by the Legislature to preserve coverage for the Medically Needy population through the MOU as a change in law favoring modification. Such funds, however, are contingent on this Court's ruling in favor of the State. A change in law that is contingent on a specific ruling by this Court cannot be considered as a change in circumstance for purposes of modification because, by its very nature, it does not exist.

iii. Change In State Government

The State argues that an electoral change in the State government in and of itself may also be sufficient to warrant modification of a consent decree. See Rufo, 502 U.S. at 392 ("To refuse modification of a decree is to bind all future officers of the state, regardless of their view of the necessity of relief from one or more provisions of a decree that might not have been entered had the matter been litigated to its conclusion."). An electoral change in the State government standing alone, however, does not warrant modification if the consent decree is

limited to reasonable and necessary implementations of federal law. Frew, 540 U.S. at 441-42 (advocating the restriction of consent decrees "to reasonable and necessary implementations of federal law, [to avoid] improperly depriv[ing] future officials of their designated legislative and executive powers . . . [, because a state] . . . depends upon successor officials, both appointed and elected, to bring new insights and solutions to problems of allocating revenues and resources."). Although the 2003 Consent Decree generally hews closely to federal due process requirements, it does expand certain requirements. The expansions, however, were reasonable and necessary implementations of federal law aimed at increasing the State's compliance with federal law. (See Doc. Nos. 868, 908.) The electoral change in State government in and of itself did not cure the State's non-compliance and, therefore, cannot be the source of modification.

Defendants' remaining arguments underlying this theory also fail. Defendants state that "Governor Bredesen took office in January 2003, after the Consent Decree in its current form was entered in 1999, and well after the original consent decree in this litigation was entered in 1996." (Doc. No. 1241 at 124) (emphasis added). Defendants are correct in pointing out that the 2003 Consent Decree has its roots in the 1996 Agreed Order. The 1996 Agreed Order was significantly revised and expanded in 1999, and further clarified in 2000 resulting in the 2000 Consent Decree. While this occurred before the current administration took office, Defendants omit a crucial fact: the 2003 Consent Decree in its current form was agreed to and entered eight months after the current administration took office.

The Defendants, however, assert that "[a]ny contention that the relevant provisions of the [2003 Consent Decree] . . . were agreed to in the fall of 2003, when the parties entered the 'global settlement' resolving specific issues associated with various consent decrees governing

TennCare, including one narrow aspect of the pharmacy provision in the [2003 Consent Decree] . . . is untenable." (Id. at 125.) The fact that all provisions of the 2003 Consent Decree were not agreed to specifically by this administration is of no avail.

It is undisputed that upon taking office, the Governor was concerned that his administration was bound by consent decrees signed by a previous administration, and that these decrees were preventing his administration's effective management of the TennCare program. (Doc. No. 1172, Tr. at 698; Doc. No. 1170, Tr. at 805-08.) This concern drove the administration to open negotiations with Plaintiffs to revise the 2000 Consent Decree, in addition to discussing the three other class actions involving different aspects of the TennCare program. (Doc. No. 1170, Tr. at 812.) A six-month, detailed negotiation ensued in which the administration successfully renegotiated pharmacy and other provisions of the 2000 Consent Decree, and entered into a "global settlement" relating to all four of the class actions involving TennCare.

With respect to this case, although the administration focused on revising the pharmacy provisions, primarily sought changes that would reap larger cost savings, and did not obtain all the changes it desired (Id. at 812-15), it had sufficient time and opportunity to raise all the issues with which it was concerned (Doc. No. 1172, Tr. at 709-11). In light of the comprehensive nature, length and purpose of the negotiations, this Court does not accept that the administration only sought to revise "one narrow aspect of the pharmacy provision." (Doc. No. 1241 at 125.) Tellingly, the Joint Motion to Approve Modification of the [2003] Revised Consent Decree includes revisions to other aspects of the 2000 Consent Decree, indicating that the parties did discuss and modify other provisions. (See Doc. No. 887.) Finally, nothing prevented this

administration from filing a motion to modify the 2000 Consent Decree in the fall of 2003 to obtain the remaining modifications it desired. Indeed, such a motion was already pending before this Court. (See Doc. Nos. 858, 859.)

These facts undermine the Defendants' theory that the 2003 Consent Decree is the type of longstanding agreement binding future state officials that is frowned upon by Rufo and Frew. Here the State had the opportunity to, and did, revise significant portions of the 2000 Consent Decree. That the administration did not obtain all the revisions it sought, and yet declined to seek relief from this Court, demonstrates a strategic choice and a legitimate exercise of its executive powers. After making this choice, however, the administration cannot now be heard to complain that agreements made by past administrations are improperly depriving it of its executive powers. Those past agreements were superceded when this administration accepted all the provisions – modified to the administration's satisfaction or not – of the 2003 Consent Decree.

Finally, Defendants and Defendants-Intervenors point out that in their Joint Motion to Approve Modification of the [2003] Revised Consent Decree, the parties did not waive "any rights . . . to seek or oppose further modifications of the [2003] Revised Consent Decree . . . [or] to challenge the Decree." (Doc. No. 887 at 2.) Defendants and Defendants-Intervenors assert that this language makes it clear that the State did not agree to waive its right to challenge provisions of the 2000 Consent Decree that it was unable or unwilling to revise after six months of comprehensive negotiations in 2003. This Court disagrees. For the reasons explained above, once the State accepted the 2003 Consent Decree, it accepted all of its provisions. As a result, the reservation of rights applies to the 2003 Consent Decree, not the 2000 Consent Decree.

The Court's interpretation of the reservation of rights is supported by the preamble to the 2003 Consent Decree, which states: "the Court has approved the requested changes to the revised consent decree that was entered July 31, 2000 (Doc. 630). This order incorporates the [2003] approved modifications into [the 2000 Consent Decree], which this order supersedes." (Doc. No. 908 at 1) (emphasis added). Moreover, Mr. Manual Martins, the former TennCare Director who participated in and was intimately familiar with the 2003 negotiations, stated:

> [T]here would be two extremes that would be troublesome to me in the process of the negotiations. One extreme would be that the State went in there and operated under bad faith in thinking we are just going to do this to get through. The other extreme would be that whatever we do here is forever more and no one can reopen it or challenge it. Both of those would be, I think, not my understanding of what occurred nor would they be something I would feel comfortable with . . . . [I]n the negotiations I think I raised . . . on several different times that with the changes in the financial situation of TennCare and the unpredictability of it that there needed to be some reservation made to deal with those kind of issues.

(Doc. No. 1170, Tr. at 818-19) (emphasis added). Defendants' and Defendants-Intervenors' current interpretation of the reservation of rights is what Mr. Martins rejected as an extreme position that could only be taken in bad faith. Mr. Martins was clear that the State must be permitted to modify the 2003 Consent Decree not because it did not get everything it wanted in the 2003 negotiations, but in recognition of the need to adapt in light of the volatility of TennCare's financial situation. Indeed, the testimony of those involved in the negotiations implies that the reservation was made for purposes of preserving further challenges to the pharmacy provisions that this administration had already heavily negotiated, rather than modifying other provisions that were negotiated by previous administrations. (Rosen Tr. (3/28/05) at 60-61; Doc. No. 1172, Tr. at 711-12; Doc. No. 1170, Tr. at 816-18.) In sum, the change in administration in and of itself does not warrant modification of the 2003 Consent

Decree.

As a whole, the changes in the legal circumstances do not warrant modification of the entire 2003 Consent Decree.

3. Change In Factual Circumstances

The State further urges the Court to find that modification is warranted due to the fiscal crisis that the State learned of in late 2004. Plaintiffs do not quibble with the fact that in the fall of 2004 the State learned that TennCare would face a serious financial crisis by fiscal year 2006. Instead, Plaintiffs assert that the financial crisis was not unprecedented and was foreseen by the State.

The key to modification of the 2003 Consent Decree is whether the fiscal crisis that the State learned of in late 2004 is different from TennCare's general financial malaise, thereby constituting a significant change in circumstances. If it is different, the Court must determine whether the fiscal crisis was foreseeable in mid to late 2003, at the time the parties agreed to the Decree. For the following reasons, the Court finds that there has been a significant change in the factual circumstances, namely the worsening of TennCare's fiscal crisis, to warrant modification of the 2003 Consent Decree. Notwithstanding the fiscal crisis, the public interest in long-term reform to systematic problems in TennCare also supports modification.

i. Fiscal Crisis Warrants Modification

Although TennCare has always faced financial difficulties, and the State was aware of TennCare's financial problems, it was not cognizant of the severity of these fiscal problems at

the time it negotiated and agreed to the 2003 Consent Decree. The McKinsey reports, which were published after the 2003 Consent Decree was entered, brought into sharp focus the long-term financial viability of TennCare. Indeed, Commissioner Goetz testified that having just instituted pharmacy reforms that would garner significant savings, the State was taken off-guard by McKinsey's dire prognosis. Most importantly, however, the enormity of the fiscal crisis was not discovered until the fall of 2004 after the State learned both that it would be losing approximately $140 million in federal Medicaid funding and that pharmacy and medical utilization rates had increased sharply. Not only were these events unpredicted and unforeseeable, but they also created an unprecedented fiscal shortfall. In fact, TennCare faced, under conservative estimates, a shortfall of $650 million in fiscal year 2006, compared to a shortfall of approximately $130 million in fiscal year 2005, and a shortfall of $200-300 million in fiscal year 2003.

Accordingly, the Court finds that the worsening in TennCare's financial circumstances was not entirely understood at the time the 2003 Consent Decree was entered and approved, and did not truly culminate until a year after the Decree's entry. Simply put, the fiscal crisis was unpredictable, unforeseeable, and unprecedented. This change in TennCare's finances represents a significant change in the factual circumstances warranting modification of the 2003 Consent Decree.

ii. Fiscal Crisis Averted?

Plaintiffs dispute the notion that TennCare faces a fiscal crisis. Instead, Plaintiffs contend that the trends in the State's overall financial condition do not support modification.

Plaintiffs argue that the State's overall fiscal health is better now than it was in 2003 due to numerous factors. First, the State expects to close out the fiscal year that ended June 30, 2005 with a surplus of about $140 million of nonrecurring funds. Second, the State's Rainy Day Fund is at the highest levels in history. Third, the TennCare program is carrying reserves of approximately $200 million in fiscal year 2006, the highest it has been in recent history. Fourth, disenrollments of 323,000 of the sickest and most expensive adult beneficiaries of TennCare have reduced the acute nature of TennCare's fiscal crisis. Finally, the State has acknowledged that it settled a lawsuit with the federal government, gaining approximately $50 million in nonrecurring funds previously earmarked to cover this contingent liability.

However, the disenrollments, and the increase in the State's Rainy Day Fund and TennCare's reserves are all steps that the State has had to take in order to combat the severe deficit that TennCare is facing. It would have been grossly irresponsible for the State not to have taken any action to set aside funds to deal with the predicted $650 million deficit. In addition, the fact that the State now has approximately $190 million in nonrecurring funds is also of no avail, as these funds have been allocated to the Health Care Safety Net Funding and the Medically Needy population, both of which represent the State's efforts to respond to potential downstream costs of the State's disenrollment policy. These actions are therefore a part of the State's overall reform plan to alleviate the fiscal crisis, and are akin to the State's proposed modifications to the 2003 Consent Decree. Accordingly, they cannot be considered "changed circumstances" for purposes of modification.

Furthermore, the proposed modifications to the 2003 Consent Decree are long-term reforms, whereas the increase in the Rainy Day Fund, the increase in TennCare's reserves, the

creation of the Health Care Safety Net Funding, and funding for the Medically Needy population are short-term financial patches that will have to be recalculated each year. Most importantly, the underlying factors that led to the crisis – systemic problems in TennCare coupled with a reduction in federal funding, higher than expected pharmacy and medical utilization rates – are not resolved by the State's monetary fixes to date. Plaintiffs agree with Defendants that the underlying factors must be addressed and TennCare must be reformed; they simply disagree about the method of reform. It would be contrary to the public interest to ignore the fact that TennCare requires long-term reform simply because the State has possibly averted the financial crisis for fiscal year 2006.

iii. Alternative Reforms

Plaintiffs further argue that modification is not warranted because when the parties entered negotiations in March 2003, the State was well aware that TennCare faced financial challenges and required reform, especially with respect to pharmaceutical benefits. According to Plaintiffs, the McKinsey reports simply confirmed what was already known: that TennCare could not be sustained without significant reform. Thus, Plaintiffs agree that reform of TennCare is necessary for the program to remain viable, but fault the State for failing to enact reforms that do not require modification of the 2003 Consent Decree, claiming that such reforms would have stabilized TennCare's financial situation.

Plaintiffs' argument that the fiscal crisis was avoidable through alternative reforms is unpersuasive. To begin with, the State did consider and institute alternative reforms, such as retrospective drug utilization review, reduction of administrative rate reductions for MCOs,

returning the MCOs to financial risk, joining a multi-state drug pooling arrangement, reducing provider rates, and increasing fraud and abuse prevention efforts, among others. Defendants contend that none of these reform measures could be implemented, individually or collectively, in time to achieve the savings necessary to address the $650 million budget shortfall. Plaintiffs also appear to have conceded that their proposed reforms would not "dramatically alter the TennCare budget situation, but they are worthy of consideration in their own right." (Def. Ex. 73 at 1.)

Importantly, it appears to this Court that these alternative reform measures could not effectively tackle the crux of the State's problem: that of sustaining one of the nation's most progressive and generous Medicaid programs in a state that has one of the nation's lowest tax burdens per person. As the Defendants correctly point out, however, the Governor was elected on the basis of a pledge not to raise taxes. Similarly, the administration and the Legislature are opposed to solving TennCare's financial problems with new taxes, resulting in a lack of support for bills that could have generated additional revenue for TennCare through taxes. In short, it appears that elected state officials believe that it is politically feasible to limit TennCare eligibility and benefits rather than impose a nominal state income tax, increase cigarette taxes or impose other taxes.

Even if this Court may disagree with that policy, it is a policy choice that "must be left to the elected representatives of the residents of the State." Rosen, 410 F.3d at 933. Therefore, it is not this Court's role to question the State's choice of reform, as long as such choice complies with the law. The Court will address the legality of the proposed modifications in Part II.C., infra. In addition, the evidence demonstrates that the State acted responsibly and in good faith in

choosing its reform measures. It took TennCare reform seriously, performed a comprehensive study of its failures and proposed reforms to address such failures. The State included numerous healthcare stakeholders and the public in its decision-making process. (See Def. Ex. 83 (stating that the State's reforms were "done with broad consultation and input from key constituency groups as well as elected and appointed officials over a period of time that are well informed of the options available to the state as it faces great budgetary challenges.").) Notably, the State actively engaged the Plaintiffs in its reform process. Finally, the Court heard from Commissioner of Finance and Administration for the State of Tennessee, Mr. Merritt Davis Goetz, Jr.; Deputy Commissioner of Finance and Administration and the Director of the TennCare Bureau, Dr. Jason David Hickey; Chief Medical Officer of the TennCare Bureau, Dr. Wendy Long; Assistant Commissioner and Chief Administrative Officer for the TennCare Bureau, Ms. Patti Killingsworth; Chief Financial Officer of the TennCare Bureau, Mr. Darin Gordon; and Budget Director for the TennCare Bureau, Mr. Scott Pierce. The Court found these witnesses to be credible, thoughtful, knowledgeable, and cognizant of their duty of balancing the State's finite resources against the welfare of TennCare enrollees. As a result, the State's choice of reform is not a bar to modification. To the contrary, the overall change in factual circumstances and the public interest warrant modification of the 2003 Consent Decree.

4. Costs Associated With The 2003 Consent Decree Warrant Modification

Defendants contend that separate and apart from the fiscal crisis, modification of the 2003 Consent Decree is warranted because the Decree is unworkable and unnecessarily burdensome. Defendants claim that the "heightened restrictions on appeal rights for both

pharmacy and medical services have given rise to abuse, unnecessary costs, poor medical outcomes in many cases, and general dysfunction." (Doc. No. 1087 at 18.) In addition, Defendants claim that their current "efforts to control costs are greatly hampered, if not doomed, to the extent" the 2003 Consent Decree remains unchanged. (Id.) To that end, Defendants conservatively estimate that the Consent Decree will save approximately $93 million in state dollars in fiscal year 2006, and similar amounts in the future.

Plaintiffs disagree that modification of the Consent Decree will reap the savings required to alter TennCare's fiscal situation. Plaintiffs contend that Defendants have unfairly blamed the TennCare consent decrees, and principally the 2003 Consent Decree, for creating the budget crisis of $650 million dollars. In support, Plaintiffs argue that Defendants have not performed a comprehensive analysis of the costs associated with the 2003 Consent Decree, and Defendants' claim to save $93 million per year from their proposed modifications is speculative and far short of the monies required to make TennCare financially stable.

The Court agrees that the $93 million savings estimate is somewhat speculative. While the Court accepts Darin Gordon's testimony that a comprehensive review of the costs associated with the Decree would improperly divert scarce state resources (Doc. No. 1168, Tr. at 298-300), the Court notes that in the absence of such a review, the State has improperly blamed the 2003 Consent Decree for all of TennCare's fiscal woes. This is reflected in the fact that the estimated savings of $93 million from the proposed modifications to the Consent Decree barely impacts the $650 million shortfall the State faces; negating the State's argument that the 2003 Consent Decree is one of the main causes for the current TennCare fiscal crisis, the disenrollments and the State's inability to control costs and operate an effective managed care system.

In addition to the State's speculative calculations, the McKinsey reports undermine the State's theory that the Consent Decree is a key cost driver. The McKinsey reports cite pharmacy, professional services, outpatient services and growing enrollment as TennCare's key cost drivers. (See Def. Ex. 38.) The Consent Decree, however, primarily deals with appeals procedures and, to a lesser extent, prior authorization requirements for prescription drugs. Thus, the Consent Decree only deals with one of the four primary cost factors cited by McKinsey. Further, the McKinsey report itself lists the consent decrees as only one out of fourteen "root causes of TennCare's cost growth." (Id. at 28.) The other "root causes" include unlimited benefits, broad enrollment aspirations, carve-out programs, a history of subscale MCOs with inadequate medical management, general medical cost inflation, misaligned provider/consumer incentives, lack of transparency into provider outcomes, poor data availability and IT systems, difficult eligibility determination, light management care and Tennessee-specific issues such as lack of experience with managed care, high drug and services utilization, and entrepreneurial spirit within the provider community. (Id.) In light of the myriad problems facing TennCare, the Court finds the State's attempt to paint the 2003 Consent Decree as the primary factor increasing TennCare's costs to be disingenuous.

Nevertheless, there is no denying that the 2003 Consent Decree has led to some increased costs in the pharmacy area. Furthermore, the State has demonstrated that certain provisions in both the pharmacy and appeals areas are unduly burdensome or require fine-tuning, thereby warranting modification.

i. Pharmacy Costs

Tennesseans have historically been high users of pharmacy services compared to other states. For example, Tennessee has a per capita annual prescription average of 16.5 prescriptions per person whereas the national average is 10.7 prescriptions per person. (Def. Ex. 201 at 8.) Indeed, it is undisputed that drug use for the Tennessee population as a whole is the highest in the nation. Correspondingly, Tennessee's physicians write 54% more prescriptions per capita than the national average for all physicians, and 50% more than the average for the states bordering Tennessee. (Id.)

For financial reasons, these statistics are problematic for TennCare. Specifically, the rate of growth in TennCare's prescription drug costs increased steadily from 30% in 1999 to a peak of 44.7% in 2001, and then declined to 26.2% by 2004. (See Def. Ex. 373.) In comparison, the rate of growth in prescription drug costs for Blue Cross Blue Shield's commercial plans in Tennessee have decreased steadily from 17.8% in 2000 to 8% in 2004. (Id.) Similarly, growth rates in CMS' prescription drug costs, which include, among others, Medicaid and Medicare prescription drug spending, was approximately 20% in 1999 and 2000, and has remained relatively steady at approximately 17% from 2001 to 2003. (Id.) Nationally, the growth rate in prescription drug costs for both public and private health plans has declined from 19.7% in 1999 to about 10.7% in 2003. (Id.) Accordingly, the growth rate in prescription drug costs in TennCare have not only fluctuated considerably, but prescription drug costs are still increasing at high rates. Both phenomena are unparalleled in Blue Cross Blue Shield commercial plans in Tennessee, CMS and national prescription drug growth rates.

Significantly, while TennCare's pharmacy growth rate may have slowed to about 26.2%,

the actual dollar amount spent on pharmacy has increased from $567,000,000 in 1999 to an astonishing $2,161,700,000 in 2004. (See Def. Ex. 374.) Thus, while the growth rate appears smaller, the amount of money spent on pharmacy continues to increase. Indeed, the first McKinsey report cited pharmacy costs as "the single most significant source of future cost increases . . ., driving nearly 60 percent of total growth through fiscal year 2008 . . . ." (Def. Ex. 38 at 29.)

While Defendants blame this growth entirely on the various consent decrees in this case, the chart Defendants rely on in support of their argument is bare-boned and conclusory, and simply looks at the compound annual rate of growth in pharmacy costs without considering the factors that could be fueling the growth. (Compare Def. Ex. 355A, with Def. Ex. 382 (listing a variety of factors explaining increase of costs for prescription drugs in Tennessee).) Indeed, it is possible that private insurers in Tennessee are able to control costs through strategies that are not appropriate in the TennCare setting such as consumer cost sharing strategies, restrictions on the pharmacies from which prescription drugs may be bought, and exclusion of other drugs entirely.

Nevertheless, the evidence taken as a whole shows that the 2000 Consent Decree was at least one of the factors that led to an increase in TennCare's prescription drug costs from 2000 to 2003. (See Def. Ex. 338 at 20 (estimating the impact of the 2000 Consent Decree for fiscal year 2004 to be approximately $130 million to $190 million); Def. Ex. 382 at 2 (stating that the increase in prescription drug cost is "partially attributable" to the 2000 Consent Decree); Doc. No. 860 at 21 (study by Applied Health Outcomes estimating that the 2000 Consent Decree increased pharmacy costs by $41 million).) Indeed, in recognition of this fact, Plaintiffs agreed to revise the provision dealing with prior authorization, which resulted in the 2003 Consent

Decree. Notably, the State and Plaintiffs agree that the State garnered savings of approximately $150-200 million from this revision. (Doc. No. 1172, Tr. at 715-16.)

Notwithstanding the changes to the 2000 Consent Decree and the concomitant savings, the fact remains that TennCare's prescription drug costs continue to increase, and are the key costs behind TennCare's ever burgeoning budget. Defendants estimate that their proposed modifications to the pharmacy provisions of the 2003 Consent Decree will result in savings of at least $7.4 million. (Def. Ex. 213.) Further, Defendants' prescription drug limit reforms are expected to save in excess of $46 million. (Id.) In light of the fiscal crisis, rising prescription drug costs, and the fact that certain aspects of the pharmacy provisions of the 2003 Consent Decree contribute to rising drug costs, see infra Part II.C.1.i.a., the Court finds that modification is warranted.

ii. Appeals

Finally, Defendants assert that the Consent Decree's myriad restrictions on the medical appeals process also block needed savings. Specifically, Defendants argue that the Consent Decree increases costs by 1) requiring the State to accept a provider's medical necessity decision; 2) requiring the State to grant appeals for services when the enrollee never requested the item or service from the MCC or when the requested service was never prescribed by a provider; 3) requiring the State to establish that a service is not supported by substantial and material evidence in the enrollee's medical records; 4) precluding the State from dismissing appeals raising no disputed issues of fact; 5) requiring the State to abide by a "prudent lay person" standard for expedited appeals; 6) prohibiting the State from appealing adverse

determinations by an Administrative Law Judge; and 7) providing coverage in the event of defective notices. Defendants contend that the "upshot [of these requirements] is to impose difficulty, expense and delays upon the State as it seeks to administer its appeals process . . . ." (Doc. No. 1241 at 39.)

Unlike the pharmacy savings, Defendants are unable to quantify the savings they would gain from changing all these appeals provisions. Defendants, however, offer three estimates that they believe will result from modification of the Decree. First, Defendants anticipate saving $8 million through the implementation of the new definition of medical necessity the State Legislature recently passed. (Def. Ex. 213.) This standard, however, is only tangentially related to the 2003 Consent Decree. Furthermore, the Court finds this calculation to be highly speculative, as the State has not provided any analysis as to why it believes the new definition of medical necessity will decrease its costs. Second, Defendants estimate saving $29 million from returning the MCOs to risk. (Id.) The State did not present credible proof that returning MCOs to risk is contingent on changing the appeals process outlined in the 2003 Consent Decree. Third, Defendants claim that if they ceased paying for non-covered services through the appeals process, they would save at a minimum $2 million. (Id.)

Defendants' savings estimates with regards to the appeals process are artificial and unsupported. Unlike the State's savings estimates regarding prescription drugs, which are based on quantifiable factors, such as the cost of drugs and past utilization rates, the State's estimates regarding appeals are based on unquantifiable factors, such as MCOs accepting additional risk and the effect of the definition of medical necessity. However, as the Court notes in Part II.C.2., infra, certain aspects of the Consent Decree's medical appeals requirements have had unintended

consequences, are unduly burdensome and are increasing administrative costs without protecting TennCare enrollees. Thus, "the public's right to the sound and efficient operation of" TennCare requires modification of certain aspects of the 2003 Consent Decree's medical appeals requirements. See Heath, 888 F.2d at 1109; see also N.Y. State Ass'n for Retarded Children, Inc., 706 F.2d at 969.

C. CERTAIN MODIFICATIONS ARE SUITABLY TAILORED TO THE CIRCUMSTANCES

Having found that modification of the 2003 Consent Decree is warranted, the remaining issue is whether each of the proposed modifications is suitably tailored to the circumstances and meets the requirements of federal law. Keeping in mind the principles of federalism, which warrant deference to state officials, the deference afforded CMS' approval of certain of the State's proposed modifications, and the legitimate financial concerns of the State, the Court finds that certain, but not all, of the modifications are suitably tailored to the circumstances and meet the requirements of federal law. The Court will discuss the suitability and legality of each modification below.

1. Prescription Drugs And Benefits

i. Defendants' Proposed Modifications (b), (e) And (g) Relating To Prior Authorization Of Prescription Drugs

Defendants contend that if the State is to have any hope of controlling pharmacy costs, it must have the authority to implement an "effective" preferred drug list ("PDL") and prior authorization system. Plaintiffs, on the other hand, argue that the State has already implemented a PDL and a prior authorization system, and that they are effective.

A PDL is comprised of drugs that are preferred by the State for various reasons. A committee of practicing pharmacists and physicians, along with the State, reviews drug classes. (Doc. No. 1171, Tr. at 879-80; 892-93.) Each drug class contains a group of drugs that have similar chemical composition and effect. (Id.) Generally, drugs in a particular class are equally effective. (Id.) Once drugs in a specific class are deemed to be equally effective, the State identifies a drug or drugs within the class that are less expensive, and designates such drugs as the State's preferred drugs for treating particular conditions. (Id.) The remaining drugs in that class are non-preferred drugs. If a physician wishes to prescribe a non-preferred drug, he or she must obtain prior authorization by making a phone call or sending a fax to First Health, the State's PBM, explaining the medical circumstances requiring the use of the non-preferred drug. (Id. at 882.) First Health may convince the physician to prescribe the preferred drug, grant the prior authorization and permit the prescription of the non-preferred drug, or deny the prior authorization. Not all drugs are subject to prior authorization. The State is currently focusing its prior authorization efforts on expensive, heavily marketed brand name drugs.

The numerous positive effects of prior authorization are undisputed. There is the much touted "sentinel" effect. That is, in light of the administrative hassle of obtaining prior authorization and the potential for receiving a denial of prior authorization, physicians are more likely to alter their prescribing practices and choose the cheaper, preferred drug over the expensive, non-preferred drug unless the latter is required for medical reasons. First Health found that in other states for every one prior authorization intervention, six other interventions were negated. (Doc. No. 1166, Tr. at 565.) Importantly, the use of the preferred drug has a direct impact on reducing pharmacy costs. For example, the average cost of a preferred drug is

$35, whereas the average cost of a non-preferred drug is $75. (Doc. No. 1235, Tr. at 1082.) Moreover, the PDL will drive market share to the preferred drugs and permit the State to negotiate better prices with pharmaceuticals. In addition to the cost savings, there are also clinical benefits to a prior authorization system. Prior authorization requires the physician to justify why the more expensive, non-preferred drug is medically necessary. Other benefits include the prevention of potentially dangerous therapeutic duplication, and dangerous and/or ineffective off-label (or non-FDA approved) usage of drugs, the implementation of dose monitoring and optimization, and quality-control measures such as drug-to-disease edits, drug-duration edits, and drug-interaction edits.

Since late 2003, Tennessee has implemented a PDL and a prior authorization system. There is evidence that physicians are generally complying with the PDL. From the standpoint of numbers of prescriptions prescribed from the PDL, Tennessee has an approximate 90 to 93% compliance rate with its PDL. (Doc. No. 1171, Tr. at 895-96.) While this average compliance rate is consistent with other states' compliance rates, compliance rates within certain high-cost drug categories are generally in the low 80% range. (Id.) Moreover, from the standpoint of the percentage of total pharmacy dollars spent on preferred, as opposed to non-preferred drugs, Tennessee has a low compliance rate of 78-79%. (See Def. Ex. 218.) This lower compliance rate has severe financial consequences.

For example, with respect to second generation antihistamines, as of January 2005, 46% of the drugs in this class were on the PDL. (See Def. Ex. 218.) The prescription compliance rate was 71%, which was substantially lower than the average PDL compliance rate. (Id.) In total, the State spent approximately $1.46 million on this category of drugs, of which $680,005 was

spent on the preferred drugs. (Id.) Significantly, the State spent $783,875 – a little more than half of the total amount – on non-preferred drugs. (Id.) Therefore, in January 2005, the State spent more on the 29% non-compliant prescriptions for second generation antihistamines than on the compliant ones.

The State has conservatively estimated that TennCare could save approximately $7.4 million annually by increasing compliance rates of six categories of drugs that have relatively low PDL compliance. (Def. Ex. 213.) As the $7.4 million figure is a result of increasing compliance in just six categories of drugs, additional savings can be reached from increasing compliance in all drug categories.

Plaintiffs dispute the State's estimates and assert that a better method of controlling prescription drug costs is through retrospective drug utilization review ("DUR"). Retrospective DUR analyzes physicians' prescription practices to identify physicians whose prescribing patterns are not in compliance with PDL requirements and good medical practice. First Health is required to notify the non-complying prescribers of their practices so that they may change their prescribing habits. Defendants, however, calculated that effective DUR will save, at most, $9 million. As a result, the evidence presented indicates that prior authorization may reap greater savings. Nevertheless, it is undisputed that effective prior authorization and effective DUR will reap the most savings. Thus, the Court recommends the State improve its DUR efforts, as the State's current DUR efforts are woefully inadequate. (See Def. Ex. 370; Doc. No. 1231, Tr. at 2374-77 (showing that First Health's current one to two page analysis of a provider's prescribing habits provides little useful information).) In addition, the Court reviews the State's proposed modifications to the prior authorization provisions of the 2003 Consent Decree to determine if

they are suitably tailored to the circumstances.

a. 2003 Consent Decree Prevents Effective Prior Authorization System

Defendants claim that Paragraph C(14) of the 2003 Consent Decree not only prevents "effective" prior authorization, but it promotes non-compliance with the PDL. Paragraph C(14) does not prohibit the creation of a PDL or prior authorization of any drug. (Doc. No. 908 ¶ C(14), at 22.) Rather, Paragraph C(14) states that a:

> beneficiary is entitled to [among other things]: (iv) An interim supply of three days[9] . . . of the prescribed drug if the pharmacist is unable, when the enrollee presents the prescription to be filled, to obtain either authorization to fill the prescription as written or the prescribing provider's authorization to substitute an alternative medication on the TennCare PDL. . . . [T]he enrollee need do nothing more than return to the pharmacy later to receive either (a) the balance of the prescription as originally written [barring any contraindications], if the prescribing provider's authorization to substitute an alternative PDL medication has not been obtained, or (2) the alternative medication authorized by the prescribing provider.

(Id. ¶ C(14), at 22-23.) The purpose of Paragraph C(14) is to protect a TennCare enrollee from a TennCare provider's failure to obtain the required prior authorization.

Defendants contend that because TennCare providers know that notwithstanding their failure to obtain prior authorization, their patients will receive not only a three-day supply of the drug that has been prescribed, but the remainder of the month's prescription upon returning to the pharmacy, TennCare providers have less incentive to prescribe drugs on the PDL or obtain prior authorization for non-preferred drugs. Defendants demonstrated that in the month of May

[9] Paragraph C(14) was modified to reduce the amount of the interim supply from two weeks to three days. (Doc. No. 908 ¶ C(14)(e), at 25.) This modification is set to expire at midnight on January 1, 2006. (Id.)

2005, TennCare enrollees presented at pharmacies approximately 65,000 prescriptions that required, but did not have, the requisite prior authorization. (See Def. Ex. 217.) Due to Paragraph C(14), a three-day supply, or the entire prescription in the case of C2 narcotics, was filled even though prior authorization was not sought or received.

This data, however, is not entirely helpful in determining the effect of Paragraph C(14) because it does not show which prescriptions would have been granted as medically necessary if prior authorization was sought, or whether the pharmacist subsequently contacted the physician, who then sought and obtained prior authorization for the remainder of the prescription. Moreover, Defendants may be partly to blame for such a high number of prescriptions reaching the pharmacist without the required prior authorization. There was credible evidence that the State has not always enforced its prior authorization policy consistently. (Doc. No. 1182, Tr. at 1926-99; see also Doc. No. 1278, Tr. at 755-59.) While this problem has since been rectified, it appears to have created a system in which physicians are unclear about the prior authorization requirements, and instead of obtaining prior authorization at the outset, they wait until the patient presents the prescription to the pharmacist, who then checks whether it requires prior authorization, and if it does, notifies the physician to obtain prior authorization. (Id.) Accordingly, it appears to the Court that the State's ineffective enforcement of the prior authorization system, in combination with Paragraph C(14)'s requirement of providing a three-day interim supply of a non-authorized prescription drug, is, at a minimum, encouraging TennCare providers to delay seeking prior authorization.

The more credible evidence that leads this Court to believe that Paragraph C(14) is encouraging non-compliance with the PDL and the prior authorization requirement is that in

May 2005, 28,777 prescriptions were filled after the expiration of the three-day period even though providers had not sought or received prior authorization. (See Def. Ex. 217.) To put this number in perspective, in May 2005, First Health received 63,683 prior authorization requests. (See Def. Ex. 216.) Assuming that each prior authorization request First Health records is for one prescription, for every two prescriptions for which physicians sought prior authorization in May 2005, there was a corresponding prescription for which physicians did not seek prior authorization. (Compare Def. Ex. 216 (showing 63,683 requests for prior authorization), with Def. Ex. 217 (showing 28,777 prescriptions filled after expiration of three-day interim supply that did not have prior authorization).) Without Paragraph C(14)(a)(iv), those prescriptions would not have been filled. Accordingly, the Court finds that the 2003 Consent Decree prevents an effective prior authorization system.

b. Defendants May Implement PDL And Prior Authorization System

In its proposed modification (b), the State requests authority to "require prior authorization by the TennCare Bureau as a condition of coverage for any drug or drug class so designated by the State." (Doc. No. 1086 at 1.) Similarly, in its proposed modification (e), the State requests that "[a]fter consultation with a Pharmacy and Therapeutics Committee established pursuant to Section 1927(d)(4)(A) of the Social Security Act, the TennCare Bureau may make all final decisions concerning the content of the formulary [also known as the PDL] and the designation of drugs available to enrollees as covered services without prior authorization." (Id. at 2.)

The 2003 Consent Decree does not prohibit the State from having a properly adopted

PDL or requiring prior authorization as a condition of coverage for any drug or drug class so designated by the State. (See Doc. No. 908 ¶ C(14), at 22-25.) Indeed, as previously noted, the State has already implemented a PDL and the prior authorization requirement since 2003. Furthermore, the 2003 Consent Decree contemplates the existence of a PDL and a prior authorization system, and the provisions relating to prior authorization simply seek to protect a TennCare enrollee from failures in the prior authorization system. (Id.) For these reasons, the State's proposed modification (e) regarding TennCare's authority to make all final decisions concerning the content of the PDL is granted, as is the portion of the State's proposed modification (b) requesting authority to require prior authorization by the TennCare Bureau as a condition of coverage for any drug or drug class so designated by the State.

c. Denial Of Reimbursement For Failure To Obtain Prior Authorization

In its proposed modification (b) the State also requests the authority to "deny any claim for reimbursement for a drug for which prior authorization is required but has not been obtained." (Doc. No. 1086 at 1-2.)

CMS has stated that "[a]ny prescription of a branded drug may be subjected to a prior authorization requirement by the State; and prior authorization will be required as a condition of coverage for branded prescription drugs that are not included on the State's Preferred Drug List ("PDL")." (See Def. Ex. 339 Att. F § II.1(A), at ii.) CMS' approval is a reflection of 42 U.S.C. § 1396r-8(d)(5), which permits the State to "require, as a condition of coverage or payment for a [drug] . . ., the approval of the drug before its dispensing for any medically accepted indication." If the State institutes a prior authorization system, it must provide a response to a request for prior authorization

within twenty-four hours, and it must provide for the dispensing of a 72-hour supply of a drug subject to prior authorization in an emergency situation. 42 U.S.C. § 1396r-8(d)(5).

The State's proposed modification goes further than CMS' approval and § 1396r-8(d)(5) by not providing for reimbursement of a 72-hour supply of a non-authorized drug during an emergency. Accordingly, the State must reimburse a pharmacist who dispenses a 72-hour supply of a non-authorized drug during an emergency.

In addition, the Court finds that categorical denial of reimbursement is overbroad and not suitably tailored to the goal of reducing costs. Further, the Court is concerned that a categorical denial of reimbursement for the dispensing of a non-authorized drug could lead to unnecessary hardship for an enrollee. The Court is concerned that a situation could arise in which a pharmacist refuses to dispense a prescription for failure to obtain prior authorization, but the enrollee nevertheless purchases all or part of the prescription because he or she believes it is an emergency or medically necessary. Under the State's proposed modification, an enrollee that seeks reimbursement for such a purchase would initially be denied reimbursement and would have to appeal the denial in order to be reimbursed. The Court finds that in light of the State's wish to reduce appeals, the fact that the provider is at fault for failing to obtain prior authorization and the potential hardship an enrollee may suffer, it is more appropriate to first review an enrollee's reimbursement request and determine whether prior authorization would have been granted. If so, the enrollee should be reimbursed. If prior authorization would have been denied, the request for reimbursement may be denied and the enrollee may file an appeal. A claim for reimbursement by providers and pharmacists may, however, be categorically denied because providers and pharmacists are aware of the prior authorization requirement, and are responsible for obtaining such authorization.

d. 72-Hour Emergency Supply Of Non-Prescribed Drug

In its proposed modification (g), the State requests authority to modify Paragraph C(14) such that:

> The State may refuse to dispense (or to reimburse a pharmacist who dispenses) a prescribed drug (or an interim supply thereof) for which prior authorization is a prerequisite to prescription as a covered service and has not been obtained, except that the State will reimburse for a 72 hour interim supply in an emergency situation. An emergency situation is a situation that, in the judgment of the dispensing pharmacist, involves an immediate threat of severe adverse consequences to the enrollee, or the continuation of immediate and severe adverse consequences to the enrollee, if an outpatient drug is not dispensed when a prescription is submitted.

(Doc. No. 1086 at 3.) Similarly, the State requests that Paragraph C(14)(e) of the 2003 Consent Decree (providing that the three day interim supply will revert to a fourteen-day interim supply on January 1, 2006) be deleted. Id. Plaintiffs complain that the State's proposed modification (g) violates federal law and is not suitably tailored to the circumstances. This Court reviews Plaintiffs' complaints regarding federal law mindful of the fact that CMS has approved the State's prior authorization procedures. (See Def. Ex. 339, Special Terms and Conditions at 3.)

Federal law permits a state Medicaid plan to require prior authorization as a condition of coverage or payment of any covered outpatient drug so long as the plan provides for the dispensing of a 72-hour supply of a covered outpatient prescription drug in an emergency situation. 42 U.S.C. § 1396r-8(d)(5)(B). Plaintiffs contend that § 1396r-8(d)(5)(B) nevertheless supports the dispensing of an "interim," as opposed to an "emergency," supply of a non-authorized prescription drug. The underlying premise of § 1396r-8(d)(5)(B), Plaintiffs assert, is that while the conflict between the prescription and the PDL is being resolved, it is more important to ensure that the patient receives the prescribed drug, than to have the patient go without treatment, and face deterioration and injury. This interpretation ignores the plain language of the statute, which only requires the dispensing of a non-

authorized drug for 72 hours "in an emergency situation." Id. (emphasis added). Although the federal statute clearly intends to protect an enrollee's health while the conflict between the prescription and the PDL is being resolved, it only wishes to do so in an emergency situation. While the refusal to dispense an "interim" supply of a non-authorized drug may unfairly penalize the enrollee for the provider's failure to obtain the required prior authorization, the federal government does not believe this penalty is significant enough to require the dispensing of an "interim" supply.

Plaintiffs further argue that the State's proposed prior authorization regime is not in the best interests of the TennCare enrollees because it restricts reasonable access to prescription drugs. See 42 U.S.C. § 1396a(a)(19) ("Eligibility for care and services under the plan will be determined . . . in a manner consistent with . . . the best interests of the recipients."); see also PhRMA v. Walsh, 538 U.S. 644 (2003). In Walsh, the Supreme Court held that a state may implement a prior authorization regime, as long as it serves Medicaid-related purposes. Walsh, 538 U.S. at 655. Justice O'Conner noted:

> Prior authorization is, by definition, a procedural obstacle to Medicaid beneficiaries' access to medically necessary prescription drugs covered under the Medicaid program. It nevertheless may serve a Medicaid purpose by 'safeguard[ing] against unnecessary utilization and assur[ing] that payments are consistent with efficiency, economy and quality of care.' A State accordingly may impose prior authorization to reduce Medicaid costs.

Id. at 685 (O'Conner, J.) (concurring with plurality's rule that "States may not impose on Medicaid beneficiaries the burdens of prior authorization in the absence of a countervailing Medicaid purpose," but dissenting from plurality's holding that Maine's prior authorization program served Medicaid-related purposes) (citations omitted).

In addition to having a Medicaid-related purpose, a prior authorization regime must not severely curtail access to prescription drugs, as that may violate the best interests of Medicaid

recipients in violation of 42 U.S.C. § 1396a(a)(19). Id. at 655. In Walsh, however, the Supreme Court's plurality opinion did not decide whether Maine's prior authorization program severely curtailed access to prescription drugs. The D.C. Circuit in PhRMA v. Thompson, 362 F.3d 817 (D.C. Cir. 2004), however, did reach this question. In Thompson, the Court found that Michigan's "Best Practices Initiative," which required prior authorization for drugs from manufacturers who refused to sign specific rebate agreements, did not curtail access to prescription drugs. 362 F.3d at 826-27. The procedures that the Thompson Court cited in finding that Michigan's prior authorization program afforded Michigan Medicaid beneficiaries reasonable and prompt access to those drugs subject to prior authorization are:

> Under the Initiative, [Michigan's PBM] immediately authorizes a prior authorization drug if (1) the drug is needed 'due to a specific medical condition or necessity, such as a drug allergy'; (2) the beneficiary has used the drug for several months and changing drugs is 'medically inadvisable'; (3) the beneficiary has tried available drugs in the class and experienced 'treatment failure or side effects'; or (4) the drug works better in combination with other medications the beneficiary uses. If the drug fits none of these categories, the request is 'immediately forwarded' to a pharmacist who 'after further conversation with the physician' either authorizes the drug or 'informs the physician of his right to appeal to a [State] physician.' If the request is not 'immediately resolved with a [State] physician,' the treating physician may prescribe an emergency 72-hour supply. Perhaps most important, at the end of the prior authorization process, 'the prescribing physician has the final say as to whether or not the requested drug will be approved' provided he can 'attest to medical necessity.'

Id. (citations omitted).

In the present case, it is clear that the State's prior authorization proposal is an attempt to reduce TennCare costs and unnecessary utilization, thereby satisfying the first prong of the Walsh rule requiring a Medicaid-related purpose. (See Def. Ex. 213; Doc. No. 1171, Tr. at 887-88, 893-94, 901-02, 914.) In addition, the prior authorization procedures outlined in Thompson are remarkably similar to the procedures that Tennessee plans to implement. Factors (1)-(4) of Michigan's Initiative

program essentially permit authorization of the drug if the physician demonstrates that it is medically necessary. Similarly, Tennessee requires that the prescribing physician explain the medical necessity of the drug before authorization is granted. (See Doc. No. 1171, Tr. at 881-83, 887-88, 902-914; Doc. No. 1235, Tr. at 1084-85; Pl. Ex. 501 § A.3.5.5., at 25.) As with Michigan's Initiative program, Tennessee's proposal to grant prior authorization of a prescription only if the treating physician explains the medical necessity of the drug does not violate the "best interest" requirement.

The only difference of import between Michigan's Initiative and Tennessee's proposal relates to the 72-hour emergency supply while the conflict between the prescription and the PDL is being resolved. Tennessee proposes that a pharmacist decide whether the situation is an emergency warranting a 72-hour supply, whereas in Michigan the treating physician may prescribe an emergency 72-hour supply. Plaintiffs argue that the Thompson Court relied on the fact that a treating physician prescribes the emergency supply as crucial in its finding that Michigan's prior authorization procedures did not violate the "best interest" requirement. That is not the case. The Thompson Court, after completing its discussion of Michigan's emergency procedures, concluded by stating: "Perhaps most important, at the end of the prior authorization process . . . the prescribing physician has the final say . . . provided he can 'attest to medical necessity.'" Thompson, 362 F.3d at 826-27 (emphasis added). The Thompson Court was not discussing the emergency procedures in this statement because the emergency supply is not dispensed at the "end of the prior authorization process," but in the middle of the process. This reading is further supported by the fact that in Michigan, a physician need not explain medical necessity to dispense an emergency supply, but must convince the state of the medical necessity of the drug in order to obtain final approval of the entire prescription. Accordingly, Plaintiffs' reliance on Thompson is inapposite, and this Court must

determine whether Tennessee's proposal that a pharmacist determine whether an emergency exists warranting a 72-hour supply of a non-authorized drug violates the "best interest" requirement.

Plaintiffs raise numerous objections as to why pharmacists are unable to make the emergency decision. First, Plaintiffs argue that pharmacists lack the training to judge whether a situation is an emergency. Second, practical constraints (e.g., no privacy, enrollee may be in drive-thru lane, no access to medical history) make it difficult to obtain the necessary information. Third, Plaintiffs argue that pharmacists are left to rely on the diagnosis from which it is difficult to tell whether an emergency situation exists.[10] Because a pharmacist has no incentive to deny an emergency supply of the drug, however, these concerns are minimal. The pharmacist is reimbursed for every prescription he or she dispenses, eliminating any monetary incentive to deny the drug. Further, there is nothing stopping the pharmacist from attempting to reach the prescribing physician or another physician. Moreover, the State's proposal does not preclude the physician, if her or she has not had time to obtain prior authorization or is unaware that the drug is subject to prior authorization, from noting on the prescription that in the event prior authorization is required, an emergency situation exists. Most importantly, in case of doubt, the pharmacist will err on dispensing the emergency supply of the drug. (See Doc. No. 1166, Tr. at 556-57.) For these reasons, the Court finds that permitting a pharmacist to make the emergency 72-hour supply does not severely curtail access to prescription drugs and,

[10] Plaintiffs rely, in part, on their expert's, Dr. Stephen Soumerai's, report to support their objections. On this point, however, Dr. Soumerai's expert report is unsupported by scientific evidence. Indeed, Dr. Soumerai admitted that the studies he relied on to conclude that pharmacists are not qualified to decide and/or are restricted from deciding whether an "emergency" supply of a non-authorized drug should be dispensed, did not specifically examine pharmacists making such decisions. (Doc. No. 1176, Tr. at 1342-44.) Accordingly, Dr. Soumerai's opinion with respect to the role of pharmacists in deciding whether an "emergency" supply of a non-authorized drug should be dispensed is of limited probative value.

therefore, does not violate the best interest requirement of 42. U.S.C. § 1396a(a)(19).[11]

Although proposed modification (g) meets federal requirements, the question remains whether it is suitably tailored to the circumstances of preserving resources. Plaintiffs argue that without the interim supplies, patients' health will deteriorate and this will lead to increased costs. Defendants disagree. Both parties rely on studies performed in other states to press their points. Thus, Plaintiffs point to Dr. Soumerai's expert report and testimony for support that patients' health will deteriorate and downstream costs will exceed the savings gained from refusing to dispense an "interim" supply. Dr. Soumerai's conclusions regarding the State's proposed prior authorization plan are unsupported. Most of the studies on which Dr. Soumerai relies do not discuss prior authorization. (See generally Exhibits to Pl. Exs. 1198, 1221.) Instead, Dr. Soumerai extrapolates from the studies on prescription drug limits to conclude that denying medication for the failure to obtain prior authorization compromises patients' health and leads to increased downstream costs. The effects of prescription limits, however, are different from the effects of a denial of a non-emergency, three-day supply of prescription drugs. (See Def. Ex. 378 at 1612 (stating that prior authorization is better than "other policies designed to control expenditures, such as the shifting of costs to patients or the use of highly restrictive formularies, [which] may disproportionately affect the elderly and the very ill, decrease access to essential medications, lead to undesirable drug substitutions, or increase the use of more expensive medical care.").) Moreover, the one study in Dr. Soumerai's report that does discuss

[11] The Court notes that the State did not present any evidence as to guidelines and/or education that a pharmacist will receive prior to implementing the emergency-only policy. Accordingly, the Court recommends that the State first implement a 72-hour "interim" supply policy, after which time prior authorization is required to obtain the rest of the prescription, and phase in the 72-hour "emergency" supply when guidelines have been created and pharmacists have been sufficiently educated.

prior authorization and is authored by Dr. Soumerai, among others, discusses the effect of prior authorization in the 1980s, and concludes: "Prior authorization is one type of administrative restriction . . . although no data from well-controlled studies exist to determine the impact of this policy." (Pl. Ex. 1198, Ex. I at 247) (emphasis in original). Therefore, these studies have limited value regarding the cost or savings of prior authorization.

In contrast, the Court finds the testimony of Dr. Giovannino Perri to be more persuasive. Defendants, Defendants-Intervenors and Plaintiffs-Intervenors, rely on Dr. Perri's more recent 2002 study in Michigan to show that the three-day, "emergency" only supply of a non-authorized prescription drug will not lead to significant deterioration in patients' health and will not increase downstream costs. (See Pls-Ints. Ex. 518 at 3 ("In the first year of operation of the PDL, [Michigan] reviewed any relationship between denial of a prior authorization request and the need for subsequent emergency room use or hospitalization in those beneficiaries. No relationship was found between the denial of the drug(s) and either of these services."); see also id., Ex. B.) In addition, Dr. Perri testified that Michigan has been able to garner significant savings after instituting prior authorization with a three-day, "emergency" only supply of a non-authorized prescription drug. Importantly, all parties agree that Michigan's system is a model Medicaid pharmacy program. Furthermore, Plaintiff's expert witness and former TennCare Pharmacy Director, Leo Sullivan, also authored a study evaluating the effects of a prior authorization policy involving nongeneric nonsteroidal antiinflammatory drugs ("NSAIDs") in Tennessee. (Def. Ex. 378.) Mr. Sullivan, along with the other authors of the study, concluded that prior authorization of NSAID prescriptions decreased expenditures for such prescriptions by 53%, and "there was no concomitant increase in Medicaid expenditures for other medical care." (Id. at 1612.) Thus, the evidence as a whole demonstrates that

downstream costs from prior authorization should be minimal, whereas the savings are expected to be high.

Finally, while this Court stated in February 2003 that an "interim" supply was required to protect the enrollee from systemic failures arising from the State's failure to adequately resolve the discrepancies between providers' prescriptions and the formulary, the Court believes that the circumstances have changed significantly making this protection less necessary. First, in February 2003, the State did not have a streamlined PDL. Second, First Health has shown that it is capable of successfully administrating a fast and efficient prior authorization system in other states, and will do so in Tennessee. (See Pls-Ints. Ex. 518.) Third, both parties agreed that from the standpoint of prescriptions prescribed from the PDL there is 90 to 93% provider compliance, and simply disagreed about the financial impact of the non-compliance. Because most providers are generally complying with the PDL and the prior authorization requirements, there is less need for the heightened protection of an "interim" supply. (See Doc. No. 1166, Tr. at 564-65.) In contrast, in light of the fiscal crisis, and the fact that the Court has found the financial impact of the non-compliance to be severe, it is appropriate for the Decree to be modified to implement an "emergency" only supply.

Finally, Plaintiffs do not object to deleting Paragraph C(14)(e) of the 2003 Consent Decree, which requires a return to a fourteen-day interim supply, and the Court finds that such a modification is necessary in light of the other modifications relating to prior authorization.

ii. Defendants' Proposed Modifications (c), (f), (h) And (i) Relating To Benefit Limits

In addition to requiring an "effective" prior authorization system, the State wishes to implement a series of benefit limits to control costs and utilization of prescription drugs, as well as

medical services. Accordingly, the State's proposed modification (c) seeks to implement a five-prescription-per-month limitation pursuant to which at least three prescriptions must be generic. Any branded prescriptions are subject to the PDL pursuant to which non-preferred prescriptions will require prior authorization by the TennCare Bureau as a condition of coverage. There is a major exemption to this five-prescription-per-month limit. The TennCare Bureau has established a "shortlist" encompassing approximately 188 drugs that do not count toward either the five-prescription-per-month limit or the two-brand-per-month limit. (See Def. Ex. 256-57; see also Def. Ex. 339, Special Terms and Conditions at 2-3.) As a result, drugs on the shortlist continue to be available to patients even after they have reached their five-prescription-per-month limit. The shortlist was developed by the TennCare Bureau in recognition of the fact that patients with certain chronic conditions would need more than five drugs per month. (Doc. No. 1235, Tr. at 1099-1100.) The State has predicted that the savings associated with this five-prescription-per-month limit is $46 million in State dollars. (See Def. Ex. 213; Doc. No. 1168, Tr. at 335-36.)

The State requests three other modifications regarding benefit limits. First, the State's proposed modification (f) requests permission to categorically exclude coverage for any over-the-counter drug. Second, the State's proposed modification (h) requests permission to impose benefit limits capping the number of in-patient hospital days per year, physician services per year, outpatient facility services per year, laboratory and x-ray services per year, inpatient and outpatient substance abuse services over the course of the enrollee's lifetime, and/or prescriptions per month that will be covered by TennCare, and to deny any claim for services or reimbursement for services whenever such service would exceed a benefit limit imposed by the State. Third, the State's proposed modification (i) seeks to impose and/or increase the co-pays charged for any TennCare service, and

deny any claim for services for which the co-pay has not been paid. Defendants assert that proposed modifications (c), (f), (h) and (i) are in fact "clarifications" because the 2003 Consent Decree does not preclude the State from implementing benefit limits or co-payments.

a. Co-Payments And Exclusion Of Over-The-Counter Drugs Permissible

Defendants correctly point out, and Plaintiffs agree, that the 2003 Consent Decree does not prohibit the State's right to implement co-payments CMS approves pursuant to the State's waiver application. On the contrary, the 2003 Consent Decree specifically reserves the State's right to implement co-payments by stating that the surviving provisions of previous decrees in this case "do not limit the ability of the defendants or their contractors to collect co-payments or deductibles when authorized to do so by the terms of the TennCare waiver." (Doc. No. 908 § I.1., at 40-41.) Thus, the 2003 Consent Decree does not prohibit the State's proposed modification (i) regarding the implementation of co-payments. While the State may impose and/or increase the co-payments charged for any TennCare service, it must do so within the confines of federal law. See, e.g., 42 U.S.C. § 1396o; 42 C.F.R. §§ 447.15, 447.53 (prohibiting co-payments for certain individuals and permitting only "nominal" co-payments).

Similarly, Plaintiffs concede that the 2003 Consent Decree does not prohibit the State from implementing its proposed modification (f) to categorically exclude coverage for over-the-counter drugs. In addition, the Court finds that this modification does not violate federal law for the reasons identified in Part II.C.1.ii.b., infra, and is suitably tailored to the circumstances. Accordingly, the State's proposed modifications (f) and (i) are permissible.

b. Prescription And Benefit Limits Permissible

The point of contention is whether the 2003 Consent Decree precludes the State's proposed modifications (c) regarding the five-prescription-per-month limit, and (h) regarding medical services benefit limits, and whether these proposed modifications comply with federal law.

The State contends that because under the current provisions of the 2003 Consent Decree, it cannot deny a prescription drug even if the required prior authorization has not been obtained, it is necessary to implement a "hard" prescription limit. A hard limit is one for which there are no exceptions based on individual circumstances. In contrast, a "soft" limit is one in which exceptions may be granted if after a case-by-case review an individual patient demonstrates the medical necessity for an additional drug. While the State has proposed a "hard" limit, Dr. Hickey testified that if the State is able to implement "effective" prior authorization, it will move to implementing "soft" limits. (Doc. No. 1150, Tr. at 203-05.) Similarly, the State's counsel assured the Court that if the Court granted the State's proposed modifications relating to prior authorization, the State would implement "soft" limits. No such assurances have been made for medical services benefit limits. Plaintiffs agree that the State may impose "soft" benefit limits that permit exceptions as required for medical necessity based upon the needs of each TennCare beneficiary and his or her medical history, but are opposed to the "hard" benefit limits specified in the State's proposed modifications (c) and (h).

Plaintiffs argue that Paragraph C(4) of the Consent Decree does not permit the State's "hard" benefit limits. Defendants contend that Paragraph C(4) is inapplicable to the State's proposed benefit limits because it was designed to prevent MCCs from using their own numerical guidelines to determine medical necessity. Paragraph C(4) states:

> ***Individualized decisions required***. The defendants shall not employ, and shall not permit others acting on their behalf to employ utilization control guidelines or other quantitative coverage limits, whether explicit or *de facto*, unless supported by an individualized determination of medical necessity based upon the needs of each TennCare beneficiary and his or her medical history.

The plain language of Paragraph C(4) appears to prohibit the State, as well as MCCs, from employing utilization control guidelines and quantitative coverage limits. Nevertheless, the examples provided by the parties in the 2003 Consent Decree interpret Paragraph C(4) as prohibiting MCCs from using their own numerical guidelines to determine the care that should be provided. Defendants claim that these examples not only demonstrate the parties' understanding of Paragraph C(4), but also make clear that Paragraph C(4) was never intended to reach benefit limits approved by CMS pursuant to a waiver application. Indeed, although Plaintiffs now contend that Paragraph C(4) prohibits benefit limits, as recently as November 17, 2004, Plaintiffs acknowledged that "[a]part from the constraints imposed by EPSDT, . . . nothing in the consent decrees restricts the State's ability to impose benefit limits." (Pl. Ex. 253 at 7.) Plaintiffs current interpretation of Paragraph C(4) is further undermined by their concession that the State may categorically exclude coverage for over-the-counter drugs. If Paragraph C(4) truly prohibited the State from implementing benefit limits that have been approved by CMS, then exclusion, without an individualized determination of the patient's medical necessity, of over-the-counter drugs would also be prohibited. Finally, if Paragraph C(4) prohibited the State from implementing benefit limits, it would contravene the plain language of 42 C.F.R. § 440.230(d), which expressly permits a State to "place appropriate limits on a service based on . . . utilization control procedures." Accordingly, the Court finds that Paragraph C(4) does not prohibit the imposition of benefit limits as set forth in Defendants' proposed modifications (c) and (h) regarding the five-prescription-per-month limit and medical services limits, respectively.

Plaintiffs further contend that the benefit limits violate 42 U.S.C. § 1396a(a)(19) and 42 C.F.R. § 440.230. The Court, however, cannot determine whether the State's proposed medical services benefit limits comply with federal law because they were not articulated to the Court, nor have they been approved by CMS. (See Def. Ex. 339.)[12] The Court can, however, review the five-prescription-per-month limit, which the Court finds complies with 42 U.S.C. § 1396a(a)(19) and 42 C.F.R. § 440.230.

The issue is whether the State may, in the first instance, limit a TennCare enrollee's prescription drug coverage per month. The plain language of 42 C.F.R. § 440.230(d) expressly permits a State to "place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures."[13] Accordingly, the sole remaining question is whether the five-

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[12] Neither party presented evidence or legal arguments regarding the State's proposed medical services benefit limits. Therefore, although this ruling finds that medical services benefit limits are not precluded by the 2003 Consent Decree, they may, if and when they are implemented, violate federal law. Nothing precludes Plaintiffs from raising any alleged violations at that time.

[13] Section 440.230 provides in its entirety:

Sufficiency of amount, duration, and scope.

(a) The plan must specify the amount, duration, and scope of each service that it provides for–

(1) The categorically needy; and

(2) Each covered group of medically needy.

(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnoses, type of illness, or condition.

(d) The agency may place appropriate limits on a service based on such criteria as

prescription-per-month limit is in the best interests of TennCare enrollees, 42 U.S.C. § 1396a(a)(19), is "sufficient in amount, duration, and scope to reasonably achieve its purpose," 42 C.F.R. § 440.230(b), and is "appropriate," 42 C.F.R. § 440.230(d).[14] Or, as the Fifth Circuit phrased it, "whether the state may place limits [on the amount of prescription drugs] available to a recipient, even though those limits may result in a denial of some medically necessary treatment, if most recipients do not need treatment beyond that provided." Curtis v. Taylor, 625 F.2d 645, 651 (5th Cir. 1980), modified, 648 F.2d 946 (5th Cir. 1980) (holding that Florida's three-physician-visit-per-month limit did not violate federal requirements); see also Charleston Mem'l Hosp. v. Conrad, 693 F.2d 324 (4th Cir. 1982) (upholding South Carolina's reduction in inpatient hospital coverage from 40 to 18 days and outpatient hospital visits from an unlimited number to 18 per year); Virginia Hosp. Ass'n v. Kenley, 427 F. Supp. 781 (E.D. Va. 1977) (upholding Virginia's 21-day limitation on inpatient hospital coverage).

The Supreme Court endorsed this standard in Alexander v. Choate, 469 U.S. 287 (1985). In Alexander, the Supreme Court held that states have "substantial discretion to choose the proper mix

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medical necessity or on utilization control procedures.

[14] Section 440.230(c) is inapplicable because the five-prescription-per-month limit does not deny prescription drugs solely because of diagnosis, type of illness, or condition. On the contrary, it is a limit regardless of diagnosis, type of illness, or condition. Arguably the "shortlist," which includes certain drugs that are specifically exempt from the five-prescription-per-month limit discriminates based on a recipient's diagnosis, type of illness or condition. That is, drugs that are required to treat specific medical conditions or illnesses are exempt from the monthly limit. (See Doc. No. 1241 at 42 (stating that the shortlist focuses on chronic conditions such as HIV and AIDS).) Nevertheless, the shortlist does not constitute a limit, but is an exemption from such limit. Therefore, it is not a denial or reduction, but an expansion in the amount, duration, or scope of prescription drugs available per month and does not violate 42 C.F.R. § 440.230(c). See, e.g., State Medicaid Manual § 4201 (stating that additional coverage for transplant patients above normal State plan limits, would not constitute an arbitrary denial or reduction in services for other (nontransplant) recipient groups).

of amount, scope, and duration limitations on coverage as long as care and services are provided in 'the best interests of the recipients.'" Id. at 303 (citing 42 U.S.C. § 1396a(a)(19)). The Court further stated:

> Medicaid programs do not guarantee that each recipient will receive that level of health care precisely tailored to his or her particular needs. Instead, the benefit provided through Medicaid is a particular package of health care services, such as 14 days of inpatient coverage. That package of services has the general aim of assuring that individuals will receive necessary medical care, but the benefit provided remains the individual services offered – not 'adequate health care.'

Id. The Supreme Court in Alexander, therefore, found the "best interest" requirement to be satisfied as long as the Medicaid plan did not deny Medicaid beneficiaries "meaningful" access to medical services. Id. at 302-03. In accordance with this standard, the Supreme Court found that Tennessee's reduction in the number of annual days of inpatient hospital care from twenty to fourteen satisfied the "best interest" requirement because the fourteen-day limitation would serve 95% of the plaintiff class. Id. The Supreme Court recently reaffirmed this standard in PhRMA v. Walsh, 538 U.S. 644 (2003) by stating that a state's Medicaid plan will be in the recipients "best interests," as long as it does not severely curtail access to medically necessary healthcare. Id. at 664-65. In light of this standard, the Court must determine whether the five-prescription-drug-per-month limit, along with the "shortlist," denies meaningful access or severely curtails access to medically necessary prescription drugs for most TennCare enrollees.

Plaintiffs contend that the five-prescription-per-month limit does not provide medically necessary care and services to TennCare enrollees because the average TennCare beneficiary receives 6.57 prescriptions per month and 39.7% have more than 6 prescriptions per month. But the fact that the average TennCare beneficiary receives more than five prescriptions per month does not necessarily mean that more than five prescriptions per month are medically necessary for the average

TennCare beneficiary. Indeed, both Plaintiffs and Defendants agree that there is some over prescription and over utilization of prescription drugs in Tennessee, thereby undermining the argument that an average of six prescriptions per month is medically necessary for most TennCare beneficiaries. Moreover, the "shortlist" is designed to provide sufficient protection for those TennCare enrollees who have medical conditions that require more than five prescriptions per month. Indeed, one of Plaintiffs' experts, Dr. Robert Herring Jr., a physician treating TennCare patients who testified against the five-prescription-per-month limit, conceded on cross-examination that many of his patients would not need more than five prescriptions per month and that certain of his concerns regarding the limit were alleviated by the shortlist. (Doc. No. 1182, Tr. at 1867, 1885-86, 1896-98, 1901-12.)

Plaintiffs' expert, Dr. Soumerai also testified, based primarily on studies performed twenty years ago in New Hampshire, that the five-prescription-per-month limit will have a large "impact on essential and often life-sustaining medications for major chronic illness; will adversely affect the health of those with multiple physical and mental illnesses; will increase the rate of permanent institutionalization of chronically ill elders; and will increase mental health visits, rates of psychotic episodes, and partial hospitalizations and emergency mental health services among those with chronic mental illness." (Pl. Ex. 1198 at 4.)[15] Dr. Soumerai's report and testimony, however, did not consider

[15] In addition to his New Hampshire studies, Dr. Soumerai included two other articles in his report to support his conclusions. (See Pl. Ex. 1198, Exs. G-H.) The first article includes little analysis and concludes that "[t]he implementation of a more restrictive prescription limit alters prescription regimens potentially predisposing elderly Medicaid recipients to clinical consequences. Further examination of the health outcomes of these recipients is necessary." (Pl. Ex. 1198, Ex. G) (emphasis added). As such, this article does not substantiate Dr. Soumerai's conclusions. Similarly, the second article is of limited value to the present analysis because it discusses cost sharing rather than benefit limits. (See Pl. Ex. 1198, Ex. H.)

the effect of the shortlist, which exempts drugs required for essential, life-sustaining medications for chronic illnesses. Further, Dr. Soumerai's New Hampshire studies do not shed light on whether Tennessee's five-prescription-per-month limit will prevent meaningful access or severely curtail access to prescription drugs to most TennCare enrollees.

While the Court is not blind to the common sense notion that restricting drugs has the potential of worsening certain TennCare enrollees' medical conditions and increasing downstream costs, the evidence presented does not demonstrate that most TennCare enrollees will not receive medically necessary treatment or that their access to such treatment will be severely curtailed as a result of the five-prescription-per-month limit, coupled with the shortlist. At this stage, and based on the evidence presented, the five-prescription-per-month limit, along with the shortlist, does not violate 42 U.S.C. § 1396a(a)(19) or 42 C.F.R. § 440.230. The Court's conclusion is buttressed by CMS' approval of the five-prescription-per-month limit, along with the shortlist. (See Def. Ex. 339, Special Terms and Conditions at 2.)[16]

Moreover, the State has represented to this Court that it will implement a "soft" benefit limit, which all involved agree is a better solution. See supra pp. 55-56. Although the "hard" limit, along with the shortlist, skirts the boundaries of 42 U.S.C. § 1396a(a)(19) and 42 C.F.R. § 440.230, the "soft" limit appropriately balances the State's utilization control goals with the "best interests of the recipients." Indeed, it is likely that a "soft" limit will reduce the prescription and use of non-essential drugs, but will continue to permit the prescription and use of essential drugs. Furthermore, it is

[16] As with the medical benefit limits, when the five-prescription-per-month limit is implemented, nothing precludes Plaintiffs from showing that it does in fact severely curtail and/or prevent meaningful access to prescription drugs and thereby deprive most TennCare enrollees from receiving medically necessary care.

undisputed that a prescription limit will most effect those who suffer serious and/or long-term chronic medical conditions. (See Doc. No. 1153, Tr. at 147-49, 164; Doc. No. 1240 at 45.) This is a relatively small percentage of the TennCare population, but it represents the highest cost to TennCare. (Def. Ex. 201 at 27 (Defendants' expert, Dr. Harry Jacobson, explaining that less than 20% of the population is responsible for over 75% of costs due to long-term, chronic conditions).) A "soft" limit is more appropriate to controlling costs by targeting the population that is having the greatest fiscal impact, rather than imposing an inflexible limit on the entire TennCare population.

To that end, the Court expects that the State will submit with its proposed revisions to the 2003 Consent Decree, evidence that it has sought approval from CMS to implement a "soft" five-prescription-per-month limit. In addition, the Court recommends that if and when the State imposes medical services benefit limits as requested in proposed modification (h), it do so on a "soft" basis. Finally, with regard to proposed modification (c), the categorical exclusion of over-the-counter drugs, there was evidence adduced at trial that in certain cases over-the-counter drugs are as effective as prescriptions drugs and can be significantly cheaper. Accordingly, the Court also urges the State to use a "soft" exclusion for over-the-counter drugs.

2. Appeals

The State seeks to modify various aspects of the medical services and pharmacy appeals system mandated by the 2003 Consent Decree. The State alleges that the appeals "system as it currently functions not only prevents necessary and important cost savings, . . . but also undermines the State's ability to manage care and thereby interferes with quality of care." (Doc. No. 1241 at 63-64.) Plaintiffs contend that the State's proposed modifications to the appeals provisions of the 2003

Consent Decree violate TennCare enrollees' due process rights, as well as federal statutes and regulations. The Court will address each proposed modification in turn.

i. Defendants' Proposed Modifications (d), (h), (i), (j) And (m) Relating To The Appeals Process

Defendants' proposed modifications (d), (h), (i), (j) and (m) relate to notice following a denial of prior authorization, drug or service, the right to appeal such denial, and the subject matter of the appeal. Certain of these proposed modifications are not opposed by Plaintiffs, are consistent with the 2003 Consent Decree and comply with federal law, while others are not.

a. Notice Required Following Denial Of Drug Or Service

The State is required to provide notice to TennCare applicants and recipients of their right to a hearing "[a]t the time of any action affecting" the applicants' or recipients' claim. 42 C.F.R. § 431.206(c)(2). "Action means a termination, suspension, or reduction of Medicaid eligibility or covered services." 42 C.F.R. § 431.201. The 2003 Consent Decree defines termination, suspension or reduction to include "acts or omissions on the part of the state defendants or others acting on their behalf which result in the interruption of a course of necessary clinical treatment for a continuing spell of illness or medical condition." (Doc. No. 908 ¶ B(7), at 4.) Furthermore, the 2003 Consent Decree expands the federal regulations to require "notice of an adverse action affecting medical assistance . . . ." (Doc. No. 908 ¶ C(1), at 7.) "Adverse action" includes a delay, denial, reduction, suspension or termination of TennCare benefits or "any other acts or omissions of the defendants which impair the quality, timeliness or availability of such benefits." (Doc. No. 908 ¶ B(5), at 3.)

As such, proposed modification (d) regarding the denial of prior authorization of a drug, and

proposed modification (h) regarding the denial of a claim for service or reimbursement by the State or a MCC because the enrollee has reached a benefit limit, constitutes a termination, suspension or reduction in a recipient's claim to a covered service or an adverse action affecting a covered service. Accordingly, the State is required to issue a notice to the enrollee of his or her right to a hearing. See 42 C.F.R. § 431.206(c)(2); (Doc. No. 908 ¶¶ B(5), C(1), at 3-4, 7). With regard to notices of denials of prior authorization, such notices may be issued through the State's PBM.

b. Timing Of Required Notice

Section 431.206(c)(2) requires the State to inform an applicant or recipient of his or her right to a hearing "[a]t the time of any action affecting his or her claim." With regard to prior authorization, 42 U.S.C. § 1396r-8(d)(5) requires that the State provide a response, including a denial, within twenty-four hours of a request for prior authorization. CMS has construed this to require written notice to both the enrollee and the enrollee's provider within twenty-four hours of receipt of a completed prior authorization request. (Def. Ex. 339 Att. F § II.2(B), at iii.) Accordingly, the State must issue a notice informing the enrollee of the basis for the denial at the time the request is denied, which may be after the service has been denied by a provider, but within twenty-four hours of receipt of a completed prior authorization request. The content of the notice must conform to the requirements of 42 C.F.R. §§ 431.206-210, as clarified by Paragraph C(1) of the 2003 Consent Decree.

Plaintiffs contend that notice within twenty-four hours after the denial of prior authorization is appropriate except when a drug that has already been prescribed on an ongoing basis or with unlimited refills later becomes subject to prior authorization. Plaintiffs assert that Paragraph C(2)(c)

of the 2003 Consent Decree requires notice when a service is prescribed "on an ongoing basis or with no specific ending date and the service is subject to a prior authorization requirement." (Doc. No. 908 ¶ C(2)(c), at 10.)

Paragraph C(2)(c) is an expansion of 42 C.F.R. § 431.206(c)(2), as adapted by Paragraphs B(5), B(7) and C(1) of the 2003 Consent Decree, which only require notice at the time of an "action" affecting a claim. As previously noted, an "action" includes a termination, suspension or reduction of a covered service, 42 C.F.R. §§ 431.201, 431.206(c)(2), delay, denial or any impairment of the quality, timeliness or availability of a covered service, (Doc. No. 908 ¶ B(5), at 3), or any interruption of a covered service (Doc. No. 908 ¶ B(7), at 4). When a drug becomes subject to prior authorization, there is no termination, suspension, reduction, delay, denial, impairment or interruption of the drug. That occurs at the time of denial of prior authorization. Therefore, Paragraph C(2)(c) expands the definition of an "action" to include the fact that a drug becomes subject to prior authorization. The State proposes to limit this expansion of the federal regulations, and the Court finds the limitation to be appropriate.

Notice that an ongoing prescription has become subject to prior authorization is reasonable given the likelihood of a busy physician overlooking the fact that a previously written prescription later becomes subject to prior authorization. However, it is also an onerous requirement for the State and undermines the State's reforms to create an effective prior authorization regime by reducing provider responsibility and discouraging provider-enrollee communication. Furthermore, there are other less burdensome prophylactic measures the State can implement to foster communication between the treating physician and the enrollee to ensure prior authorization is timely received and

limit interruptions in refilling prescriptions.[17] Thus, the State is not required to provide notice of the fact that a drug, prescribed on an on-going basis, has become subject to prior authorization.[18] In sum, the Court finds that the portion of the State's proposed modification (d) regarding issuing the notice within twenty-four hours of a denial of prior authorization of a drug is suitably tailored to the circumstances.

Similarly, with regard to denial of a drug or service due to benefit limits, the State or MCC must issue a notice at the time of the denial. 42 C.F.R. § 431.206(c)(2), (see also Def. Ex. 339 Att. F § III.1(A), at iv). Further, when an enrollee is approaching or reaches a benefit limit, there is no "action" by the State because there is no termination, suspension, reduction, delay, denial, impairment or interruption of the drug or service. 42 C.F.R. §§ 431.201, 431.206(c)(2); (Doc. No. 908 at ¶¶ B(5), B(7), at 3-4). An "action" occurs at the time of the denial of the drug or service. Accordingly, the State is under no obligation to provide notice that an enrollee is approaching or reaching his or her benefit limit. Notice is only required at the time the enrollee is denied a drug or service, or reimbursement for such drug or service because he or she exceeds a particular benefit limit. Furthermore, such notice need only be provided the first time an enrollee exceeds a particular benefit limit within a particular time period, and the State or MCC need not issue repeated notices for denials of that same benefit for the remainder of the applicable period. (See Def. Ex. 339 Att. F. § III.1(A), at iv.) In the event that the State or a MCC issues a notice, but it is later determined that the enrollee

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[17] For example, the State may require pharmacists to provide a notice to enrollees at the time a prescription is refilled during the "grace period" – the period during which prior authorization is required for the drug, but the drug is not denied for failure to obtain such authorization – informing the enrollee to remind the treating physician to obtain prior authorization.

[18] Notwithstanding this ruling, Paragraph C(2)(c) is binding for all other purposes.

had not reached their benefit limit, the State or MCC must issue a new notice informing the enrollee of the basis for the denial at the time the claim is denied when the person does subsequently reach the benefit limit.

c. Provider Action Or Inaction Attributable To State

The State also wishes to preclude appeals involving provider inaction. Thus, in its proposed modification (d) the State proposes that "[w]here no prior authorization has been sought for a drug requiring such authorization in order to be treated as a covered service (and therefore no prior authorization request has been denied), there will be no State action from which a valid appeal can be taken." (Doc. No. 1086 at 2.) Similarly, in its proposed modification (h) in the context of benefit limits, the State proposes that a "provider's refusal to render a requested service because the enrollee has reached a benefit limit does not, on its own, constitute action by the State, and the State need not provide notice in those circumstances." (Id. at 3.) Finally, in its proposed modification (i) in the context of co-payments, the State proposes that a "provider's refusal to provide a requested service because the enrollee did not pay the co-pay does not constitute action by the State, and the State need not provide notice in those circumstances." (Id. at 4.)

Contrary to the State's assertion, CMS does not provide any guidance whether the provider's failure to obtain the required prior authorization, refusal to render a service because an enrollee has reached a benefit limit, or refusal to provide a service because the enrollee did not pay the co-pay constitutes state action, thereby triggering the federal notice requirements. (See Def. Ex. 339 Att. F,

at ii-vi.)[19] As a result, the narrow question before the Court is whether the provider's failure to obtain prior authorization or refusal to render services because an enrollee has reached a benefit limit or refuses to pay a co-payment, may be attributable to the State.

In TAHMO v. Grier, 262 F.3d 559, 565 (6th Cir. 2001), the Sixth Circuit held that MCOs "are subject to the control of the State insofar as they are contractually bound to follow whatever appeals and grievance procedures the State deems appropriate. Moreover, the [MCOs] are acting on behalf of the State . . . ." Accordingly, the Sixth Circuit held that because MCOs are contractors who are controlled by the State and act on behalf of the State, they are agents of the State.

Providers, in turn, are subcontractors of the TennCare program and are responsible for providing care in accordance with the rules of the TennCare program. Although there is no contract between a provider and the TennCare Bureau, providers are subject to the control of the State and act on behalf of the State. That is, just as MCOs are required to follow TennCare's appeals procedures, providers are required to comply with TennCare's rules and regulations. If not, providers may be excluded from the provider network. Similarly, providers act on behalf of the State by providing medical care. Without providers, the State could not provide medical care to enrollees. Therefore, as subcontractors of the TennCare program, providers are also agents of the State. There is ample evidence that providers are already treated as subcontractors and agents of the TennCare program.

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[19] CMS, however, made it clear that the State's failure to act upon a request for prior authorization triggers the notice and hearing requirements. (See Def. Ex. 339 Att. F § II.2(B), at iii ("State's failure to act on a request for prior authorization within a 24-hour period after receiving a submission that complies with the State's requirements for a completed prior authorization request may be deemed a denial from which the enrollee can appeal.")); see also 42 C.F.R. § 431.220(a)(1) (requiring the State to grant an opportunity for a hearing to "[a]ny applicant who requests it because his claim for services is . . . not acted upon with reasonable promptness.").

First, Dr. Long testified that providers are in effect sub-contractors of TennCare even though there is no actual contract. (Doc. No. 1183, Tr. at 1147.) Second, a series of questions posed by MCCs and answered by the State and the Plaintiffs treat providers as subcontractors by, for example, permitting them to issue notices of discharge plans; requiring providers to comply with notice provisions as a condition of participation in TennCare; and, importantly, requiring MCCs and the State to be liable for subcontractors acting on behalf of MCCs. (See Def. Ex. 699 at 3-4, 9.) Third, CMS also expects that "[p]hysicians (or other providers with prescribing authority) participating in TennCare will be responsible for requesting prior authorization, according to procedures to be established by the State." (Def. Ex. 339 Att. F § II.1(B), at ii.)

Accordingly, a provider's failure to request prior authorization, or refusal to render services because an enrollee has reached a benefit limit or refuses to pay a co-payment, is attributable to the State because a provider is a subcontractor and agent of TennCare. As such, the State is required to provide notice of an enrollee's right to a hearing and the portions of proposed modifications (d), (h), and (i) seeking to avoid such notice are denied. The State may provide notice of an enrollee's right to appeal by creating a standard, preprinted notice for distribution by providers when they refuse to render service for benefit limit and co-payment reasons.

In addition, it is especially important to preserve an enrollee's right to appeal a provider's refusal to render a requested service for failure to pay a co-payment. Federal law specifically prohibits the denial of care or service based on an individual's inability to pay a co-payment. See 42 U.S.C. § 1396o(e) ("[N]o provider participating under the State plan may deny care or services to an individual eligible for such care or services under the plan on account of such individual's inability to pay a deduction, cost sharing, or similar charge."). Federal regulations further clarify that although a

provider may not deny services to an individual eligible for services on account of the individual's inability to pay the co-payment, a provider may deny a service to an individual who is able to pay, but refuses to do so. See 42 C.F.R. §§ 447.15, 447.53. The State's proposed modification, however, does not distinguish between an individual's inability to pay rather than an individual's refusal to pay. The State simply proposes to deny any claim for services for which the co-pay has not been paid or deny notice when a provider refuses to render services because the enrollee did not pay the co-pay. Not only does the Court find this to be impermissible, but CMS has not approved this proposed modification.

The State has complained that it would not be able to process appeals arising from provider failure to obtain prior authorization, as they would be too numerous. (See Doc. No. 1258 at 3-6.) The Court is cognizant of the difficulties the administration of such appeals would create for the State. (See Doc. No. 1258 at 2-6.) As a result, the State may require enrollees to exhaust an administrative process to obtain the requisite prior authorization before commencing an appeal. Such an administrative process may entail the State (a) performing the prior authorization analysis prior to processing the appeal, consistent with subparagraph (ii) of the Revised Order (Doc. No. 1256), (b) requiring the enrollee to request his or her treating physician to obtain prior authorization, (c) assisting the enrollee in obtaining access to a physician who can obtain the required prior authorization in the event an enrollee is unable to reach his or her treating physician or does not have access to a physician, or (d) assisting the enrollee in any other manner to obtain the required prior authorization. This administrative process should be sufficient to elicit a response from a majority of providers, while at the same time protecting enrollees' right to appeal in the minority of cases in which providers are unresponsive.

The State may require an enrollee to exhaust this administrative process before the enrollee is notified of his or her right to appeal and before the enrollee may appeal, provided, however, that the State performs the administrative process with reasonable promptness. See 42 C.F.R. § 431.220(a)(1) (requiring the State to grant an opportunity for a hearing to "[a]ny applicant who requests it because his claim for services is . . . not acted upon with reasonable promptness."); see discussion on "reasonable promptness" requirement infra pp. 80-81. As the Court has previously stated, the Court declines to rule on what constitutes "reasonable promptness" in this context without reviewing the administrative process the State implements. However, the Court notes that the 2003 Consent Decree, as modified by the Court's Orders (Doc. Nos. 1256, 1261), acknowledges that it may take up to three days for a physician to obtain prior authorization. (See Doc. No. 908 ¶ C(14)(e), at 25.) Similarly, CMS requires the State to treat prior authorization requests within a twenty-four-hour period. (See Def. Ex. 339 Att. F § II.2(B), II.3(A), at iii (describing procedures for appealing denials of prior authorization).) The Court has not been presented with enough evidence to determine why a request for prior authorization received from a provider should be treated differently from one received from an enrollee, but on the evidence presented the Court is not entirely convinced that the two requests should be treated differently. Accordingly, reasonable promptness in this context may constitute, at a minimum, four days.[20]

d. Benefits During Pendency Of Appeal

The State further proposes that if an enrollee appeals the denial of prior authorization or

[20] An enrollee need not exhaust an administrative process prior to appealing a provider's refusal to render services due to a benefit limit or non-payment of a co-payment, as the State did not demonstrate that the administration of such appeals would be unduly burdensome.

denial of coverage in the event of a benefit limit, it should have no obligation to pay for the service during the pendency of the appeal. Generally, federal regulations favor maintaining or reinstating services during an appeal. See 42 C.F.R. §§ 431.230-231; see also Daniels v. Wadley, 926 F. Supp. 1305, 1308, 1310 n.7 (M.D. Tenn. 1996) (stating that agency may never terminate a Medicaid recipient's benefits prior to the completion of a fair hearing); Granato v. Bane, 74 F.3d 406, 413 (2d. Cir. 1996) (holding that services must be continued during appeal if recipient requests services within ten days of mailing of notice even in situations where advance notice is not required). Paragraph C(8) of the 2003 Consent Decree also requires continuation or reinstatement of benefits pending an appeal. (Doc. No. 908 ¶ C(8), at 16.)

Payment for a non-authorized drug during an appeal, however, is contrary to the purpose of the prior authorization program and inconsistent with 42 U.S.C. § 1396r-8(d)(5). (See also Def. Ex. 339 Att. F § II.4(A), at iv (CMS stating: "During the pendency of any appeal from denial of a pharmacy service due to the lack of required prior authorization, the enrollee . . . will not have any right to receive on a covered basis the drug that is the subject of the appeal.").) Similarly, payment of a service that has been denied due to a benefit limit, as opposed to medical necessity, is inconsistent with the purpose of benefit limits. (See Def. Ex. 339 Att. F § III.2(D), at vi (CMS stating: "The enrollee shall not receive continuation of the benefit that is the subject of the appeal . . . pending the resolution of the appeal.").) Therefore, the portions of the State's proposed modifications (d) and (h) refusing payment pending an appeal for a non-authorized drug or a service that is in excess of a benefit limit are granted.

There are two exceptions with regard to payment of a drug for which prior authorization has been denied. First, § 1396r-8(d)(5) permits a 72-hour emergency supply of a non-authorized drug.

See also Paragraph C(14)(a)-(c) of the 2003 Consent Decree (Doc. No. 908 at 22-24), as revised by subparagraph (vii) of the Revised Order (Doc. No. 1256). As a result, an enrollee is entitled to a single 72-hour emergency supply while an appeal is pending. Second, when a drug that has been prescribed on an ongoing basis or with unlimited refills later becomes subject to the prior authorization requirement and is denied such authorization, the State or its contractor must comply with Paragraph C(8) of the 2003 Consent Decree, requiring continuation or reinstatement of benefits pending an appeal. The medical risk of discontinuing an ongoing prescription outweighs the State's burden of paying for such a prescription during an appeal. Further, CMS has stated that benefits must be continued during an appeal to the extent that the State's decision not to cover the item or service is based on medical necessity. (See Def. Ex. 339 Att. F § III.2(D), at vi.) A denial of prior authorization is in effect a determination by the State that a prescribed drug is not medically necessary. While payment during an appeal of a non-authorized drug is generally inconsistent with § 1396r-8(d)(5), due to the medical risk of discontinuing an ongoing prescription, when such a prescription becomes subject to prior authorization and such authorization is denied, the State must continue paying for the prescription pending the resolution of the appeal.

Similarly, when a claim for service is denied for failure to pay the co-payment, the State must pay for the service during the pendency of any appeal from such denial because federal law specifically prohibits the denial of care or service based on an individual's inability to pay a co-payment. See 42 U.S.C. § 1396o(e); see also supra Part II.C.2.i.c. Accordingly, the portion of the State's proposed modification (i) that seeks to deny payment during the pendency of an appeal for failure to pay a co-payment is denied.

Finally, in the context of both prior authorization and benefit limits, if the enrollee ultimately

prevails on the appeal and is found to have been eligible to have received the services, the State or its contractor shall make corrective payments, retroactive to the date that the incorrect denial of coverage occurred, as required by 42 C.F.R. § 431.246 and Paragraph C(13) of the 2003 Consent Decree (Doc. No. 908 at 22), as revised by subparagraph (xv) of the Revised Order (Doc. No. 1256). (See also Def. Ex. 339 Att. F § II.4(B), at iv, § III.2(E), at vi.)

e. Enrollee Entitled To Hearing Only If There Is Valid Factual Dispute

In its proposed modifications (d), (h) and (i), the State proposes to dismiss without a hearing any appeal of a denial of prior authorization, a denial of a service based on a benefit limit, or a denial of a service based on the refusal to pay a co-payment that does not raise a valid factual dispute. CMS has already permitted the State to "dismiss any appeal that does not raise a valid factual dispute without a hearing . . . ." (Def. Ex. 339 Att. F § II.3(A), at iii; see Def. Ex. 339 Att. F § III.2(C), at v.)

Plaintiffs object to this proposed modification on the basis that it violates 42 C.F.R. § 431.220 and Paragraph C(12) of the 2003 Consent Decree. Section 431.220 provides:

> (a) The State agency must grant an opportunity for a hearing to the following:
>
> (1) Any applicant who requests it because his claim for services is denied or is not acted upon with reasonable promptness.
>
> (2) Any recipient who requests it because he or she believes the agency has taken an action erroneously.
>
> . . .
>
> (b) The agency need not grant a hearing if the sole issue is a Federal or State law requiring an automatic change adversely affecting some or all recipients.

Plaintiffs contend that § 431.220(b) does not limit the right to a hearing to"valid factual disputes," but simply excludes challenges to "law or policy." Further, Plaintiffs argue that even though §

431.220(b) does not guarantee an applicant or a recipient the right to a hearing if the only issue is one of law or policy, in order to determine if the only issue is one of law or policy, the State must hold a hearing pursuant to Paragraph C(12) of the 2003 Consent Decree.[21]

Plaintiffs' objections are reminiscent of those they raised in Rosen v. Goetz, 410 F.3d 919 (6th Cir. 2005), and which were expressly rejected by the Sixth Circuit. The Sixth Circuit has interpreted the interplay between §§ 431.220(a) and 431.220(b) as providing a "dichotomy between impermissible challenges to a State's legal or policy judgment . . . and permissible challenges to the relevant facts or application of law to a given beneficiary," respectively. Id. at 926. Therefore, contrary to Plaintiffs' assertion that § 431.220 does not include a "valid factual dispute" exception, the Sixth Circuit has specifically held that when read in combination, §§ 431.220(a)-(b) limit hearings to "valid factual disputes." Id. at 925-28.

The Sixth Circuit further clarified that "'matters of law and policy', as opposed to matters of fact or the application of law" do not require hearings under § 431.220. Id. at 926 (citing Benton v. Rhodes, 586 F.2d 1, 3 (6th Cir. 1978)) (emphasis added). Indeed, the Sixth Circuit specifically found that Plaintiffs' argument that only a hearing officer may determine whether the sole issue is one of law or policy "reads out of the regulations § 431.220(b)." Id. at 930. Accordingly, the Sixth Circuit definitively rejected Plaintiffs' argument that the State must hold a hearing to determine if the only issue is one of law or policy. Furthermore, the Court does not view Paragraph C(12) of the 2003 Consent Decree as requiring a hearing to determine if the only issue on appeal is one of law or policy.

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[21] Paragraph C(12) states: "Impartiality of appeal process. The defendants shall not compromise the impartiality and integrity of the appeal process by: . . . (e) Taking from the impartial decisionmaker the authority to decide some or all aspects of a beneficiary's appeal." (Doc. No. 908 ¶ C(12), at 21.)

Rather, when an enrollee is entitled to a hearing because he or she raises a "valid factual dispute," Paragraph C(12) prohibits the defendants from compromising the impartiality of such a hearing. Thus, pursuant to the Sixth Circuit's analysis of § 431.220 in Rosen, and its mandate to give substantial deference to CMS' approval of the State's proposal, the Court grants the State's proposal to dismiss without a hearing any appeal of a denial of prior authorization or covered service due to benefit limits and non-payment of a co-payment that does not raise a "valid factual dispute."[22]

Plaintiffs' concern that the State's interpretation of "valid factual disputes" will be too narrow and will exclude permissible challenges to relevant facts or the application of the law to the facts of the case is without basis. To the contrary, CMS has broadly defined valid factual disputes in the context of prior authorization and benefit limits as disputes that, if resolved in favor of the enrollee, would entitle the enrollee to coverage. (Def. Ex. 339 Att. F § II.3(B), at iii, § III.2(C), at v.) More specifically, in the context of prior authorization, CMS has defined a valid factual dispute to include "[a] dispute concerning whether a particular drug or dosage is medically necessary for the enrollee . . . ." (Def. Ex. 339 Att. F § II.3(B), at iii.) Further, with respect to benefit limits, CMS has defined a valid factual dispute to include an administrative error incorrectly calculating a benefit limit or a change in circumstances that has been reported to TennCare, resulting in a change in eligibility categories. (Def. Ex. 339 Att. F § III.2(C), at v-vi.) CMS has not limited "valid factual disputes" to these scenarios, but has provided them as examples. At this stage of the proceedings, the Court is satisfied that the State will appropriately apply the "valid factual dispute" standard, but nothing precludes the Plaintiffs from seeking relief from this Court in the event they are able to show that the

[22] While Plaintiffs cite to cases from other circuits that have invalidated as contrary to due process state policies seeking to limit access to hearings based on the fact-policy distinction, this Court is bound by the Sixth Circuit's decision in Rosen.

State is impermissibly depriving enrollees who raise "valid factual disputes" of their right to a hearing. Finally, Plaintiffs argue that TennCare enrollees do not have the expert knowledge to articulate the reasons why a particular service is medically necessary or why the decision to deny prior authorization, impose a benefit limit or co-payment was incorrect. Without such skills, Plaintiffs assert, TennCare enrollees' requests for a hearing could easily be construed as contesting the State's prior authorization "law or policy," rather than involving a "valid factual dispute." The Court shares Plaintiffs' concern. Nevertheless, the State assured the Sixth Circuit that in implementing the "valid factual dispute" inquiry, "a recipient will be entitled to all reasonable inferences, in other words the benefit of the doubt, in determining whether a material factual dispute has been established or whether a material dispute about the application of the regulations to a given fact pattern has been established." Id. at 929.

A statement as simple as: "I am appealing because I did not get my medicine or treatment" may raise a "valid factual dispute." Indeed, in light of the assurances the State gave to the Sixth Circuit, such a statement must be treated as raising a "valid factual dispute" because the State cannot discern whether the TennCare enrollee is challenging the prior authorization, benefit limit or co-payment policy, or whether the TennCare enrollee is challenging the policy as applied to his or her factual case. Furthermore, at the time of a denial of prior authorization or benefits, it is unlikely that the enrollee will solely challenge the State's policy without raising any factual issues as to why the State's policy does not apply to his or her case. Thus, in the context of an individualized challenge to a denial of prior authorization, benefits or services, it will be the rare case indeed that is dismissed for failure to raise a "valid factual dispute."

In addition, the State in its proposed modification (m) seeks to implement a screening process

to identify appeals that are not based upon a valid factual dispute (i.e., an individualized dispute that, if resolved in favor of the enrollee, would entitle the enrollee to coverage of the service sought in the appeal), and dismiss such appeals without providing a hearing. Rosen left no doubt that the State may implement such a screening process. 410 F.3d at 930 (finding that the State may create a screening process to determine whether "the agency need not grant a hearing" pursuant to § 431.220(b)).

Lastly, the State proposes in its modification (j) that upon implementation of any benefit reforms to the TennCare program, if the State provides notice to all enrollees that complies with federal requirements and the terms of the TennCare waiver and the State provides enrollees an opportunity for a hearing on any valid factual dispute regarding the application of the benefit reform to them (i.e., issues related to their eligibility category), then the State may refuse to consider, as a ground for an appeal of a service denial, challenges to an enrollee's eligibility category that they had the opportunity to raise previously. Neither federal law nor the 2003 Consent Decree prohibits this course of action and CMS has specifically endorsed it. (See Def. Ex. 339 Att. F. § I.2.(E), at ii ("If the enrollee does not appeal prior to the effective date of changes in coverage as identified in the Benefit Notice, such changes in benefits will become effective . . . .").) As TennCare enrollees are not sophisticated consumers of medical care, the Court finds that if an enrollee can show excusable neglect for not previously raising the eligibility category challenge, the State must allow the appeal. The State may implement an administrative process to determine whether there is excusable neglect preventing a previous challenge to an eligibility category.

ii. Defendants' Proposed Modifications (k) Relating To Appeals Lacking A Prescription

In its proposed modification (k), the State seeks to delete Paragraph C(10)(b) and reduce the scope of Paragraphs B(5)-(6) of the 2003 Consent Decree to permit the dismissal of an appeal without providing a hearing when the enrollee never requested the item or service sought in the appeal from the MCC in the first instance or when the item or service sought has not been ordered or prescribed by a provider.

Paragraph C(10)(b) of the 2003 Consent Decree prohibits the State from "[r]efusing to provide an appeal because the beneficiary lacks an order or prescription from a provider supporting the appeal." (Doc. No. 908 ¶ C(10)(b), at 19.) In addition, Paragraph B(5) expands the definition of an appealable State "action" to include any delay or denial of TennCare benefits, as well as any other acts or omissions of the Defendants which impair the quality, timeliness or availability of such benefits. (Id. ¶ B(5), at 3-4.) Paragraph B(6) also defines "delay" as any "delay in receipt of TennCare services, and no specific waiting period may be required before the beneficiary can appeal." (Id. ¶ B(6), at 4.)

Defendants argue that this modification is necessary because appeals by enrollees for services that have not been requested from an MCC or prescribed by a provider place an unwarranted burden on the appeals system, interfere with the managed care relationship, and are contrary to federal law. Plaintiffs, on the other hand, argue that Paragraphs B(5)-(6) and C(10)(b) are crucial because they permit enrollees to address systemic deficiencies or inadequate provider network, challenge improper pressure placed on providers to avoid prescribing medically necessary care, and hold MCCs responsible when they fail to provide services. In addition, Plaintiffs contend that federal law requires that the State grant an enrollee a hearing in the event of a denial of benefits or services regardless of

whether the TennCare enrollee has an order or prescription from a provider.

Both Plaintiffs and Defendants claim support for their positions in federal law. Defendants, although not entirely specific on what federal law they rely, presumably invoke 42 C.F.R. § 431.206(c)(2), which requires the State to provide notice to applicants and recipients of their right to a hearing at the time of any action affecting an applicant's or recipient's claim. (See Doc. No. 1241 at 67.) The State's argument appears to be that when a TennCare enrollee lacks an order or prescription from a provider or MCC, there is no state action. If there is no state action, the State does not have to provide notice pursuant to § 431.206(c)(2), and because the State does not have to provide notice, the TennCare enrollee has no right to appeal. The State's reliance on § 431.206(c)(2) is of limited value.

Section 431.206(c)(2) read in combination with 42 U.S.C. § 1396a(a)(3) and 42 C.F.R. § 431.220(a) demonstrates that federal law considers State inaction in certain circumstances to constitute state action from which a TennCare enrollee may appeal. Section 1396a(a)(3) provides that a "State plan for medical assistance must . . . provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan . . . is not acted upon with reasonable promptness." Section 431.220(a) reiterates this requirement by stating that the State "must grant an opportunity for a hearing to . . . [a]ny applicant who requests it because his claim for services . . . is not acted upon with reasonable promptness." Thus, federal law permits a TennCare enrollee to appeal when he or she has made a claim for a medical service or prescription, and the claim has not been acted upon with reasonable promptness. CMS appears to support this interpretation because it has made clear in the context of prior authorization that the State's failure to act upon a request for prior authorization within twenty-four hours triggers the notice and hearing requirements. (Def. Ex. 339 Att. F § II.2(B), at iii; see also Pl. Ex. 1218 (Georgia statute

stating "[a]ny applicant for medical assistance whose application . . . is not acted upon with reasonable promptness . . . shall be entitled to a hearing . . . .").)

Accordingly, the second part of the State's proposed modification (k) prohibiting an appeal when the item or service sought has not been ordered or prescribed by a provider is contrary to federal law because it encompasses situations in which an enrollee may be requesting an item or service and the State or its contractors are not acting on the request with reasonable promptness. This inaction constitutes state action triggering an enrollee's appeal rights. As the latter part of the State's proposed modification (k) violates federal law, it is denied.

In contrast, the first part of the State's proposed modification (k) prohibiting an appeal when the enrollee never requested the item or service in the first instance does not contravene federal law. Section 431.220(a) does not make all State inaction appealable. Rather, the TennCare enrollee is required first to make a claim for services and only if the State or its contractors do not act with "reasonable promptness," then an enrollee has the right to appeal. Nevertheless, the 2003 Consent Decree has expanded federal regulations by defining an appealable action to include any delay or denial of TennCare benefits, as well as any other acts or omissions of the Defendants which impair the quality, timeliness or availability of such benefits. (Doc. No. 908 ¶¶ B(5)-(6), at 3-4.) While Defendants' proposed modification (k) seeks to whittle away at this definition, Defendants have not sought to do away with it completely. Furthermore, for the reasons stated below, the Court finds that proposed modification (k) that seeks to curtail the expansion of federal law in Paragraphs B(5)-(6) and C(10) is not suitably tailored to the circumstances.

In approving the 2000 Consent Decree, the Court found that these provisions were included to address situations in which an enrollee lacked access to a provider and could not obtain a prescription

or providers were under pressure from health plans not to prescribe medically necessary care. (Doc. No. 868 at 12.) There is no question that network and provider access problems continue to this date. One indicator of network and/or provider access inadequacies is the number of appeals filed by enrollees to change MCCs. Dr. Long testified that MCC change requests drastically out number all other categories of appeals, and these are sought because patients are unable to get access to a provider within the network of the MCC to which they are assigned, among other reasons. (Doc. No. 1174, Tr. at 1241.) Ms. Killingsworth also testified that for a variety of reasons, MCC change requests have traditionally been the largest volume of appeals. (Doc. No. 1189, Tr. at 2011.) Schaller Anderson of Tennessee, LLC, the organization that tracks and compiles data on TennCare appeals, reported that from May 2004 to May 2005 out of a total of 41,378 appeals, 17,390 or 42% represented MCC change requests. Even if all the MCC change request appeals are not due to network and/or provider access inadequacies, the sheer number of such appeals demonstrates that network and/or provider access problems still exist.

The State, however, argues that independent of MCC change requests, almost 44% of appeals for medical services from April 2004 to April 2005 were first-time requests. (Def. Ex. 351.) The State contends that many such appeals represent frivolous claims by enrollees who are incapable of locating a prescriber willing to support the service or drug sought. (Doc. No. 1183, Tr. at 1141-43.) The Court disagrees. Even accepting that some appeals lacking a prescription may be frivolous, there was sufficient evidence to demonstrate that there is a legitimate need for such appeals. For example, Plaintiffs presented testimony by TennCare enrollees demonstrating the acute need for the right to such appeals in the case of children with autism and related behavioral issues. In those cases, TennCare covered services for autism, but all State contractors denied care because it was not clear

which contractor was responsible for providing services to treat autism. (See Doc. No. 1172, Tr. at 690-93; Doc. No. 1183, Tr. at 1136-41; Doc. No. 1207, Tr. at 2758-65; Doc. No. 1232, Tr. at 2770-72; Doc. No. 1216, Tr. at 3054-3085; Pl. Ex. 583-583A; Pl. Ex. 586-586A.) The children received the services only after appealing. (Id.) These cases, as well as inadequate provider networks making it difficult or impossible for an enrollee to obtain a prescription or order, demonstrate the need for the right to appeal without a prescription.

The State argues that the burden of processing such appeals exacts a "profound toll on the resources and administrative functioning of the TennCare appeals program." (Doc. No. 1241 at 67.) Nevertheless, the State's estimate that it processes $2 million worth of frivolous claims does not represent a "profound" toll on TennCare's resources in light of TennCare's overall budget of $8 billion. (Def. Ex. 213.) In balancing the enrollee's right to an appeal, on the one hand, and the State's fiscal problems, on the other hand, the Court finds that it is appropriate for the State to create an administrative grievance or other informal process to address appeals by enrollees without a prescription or a service. The State may require an enrollee to exhaust this administrative grievance or informal process before the enrollee's appeal can continue. However, the administrative process must be completed with reasonable promptness, because once the enrollee has filed an appeal he or she has made a claim for services triggering the requirements of 42 C.F.R. § 431.220(a).

iii. Defendants' Proposed Modifications (l), (n), And (r) Relating To Evidence Relied Upon In Medical Appeals, Burden Of Proof And Definition Of Medical Necessity

The Defendants make three inter-related requests regarding the evidence permitted to support medical necessity and medical appeals, which party bears the burden of proving medical necessity,

and the definition of medical necessity.

First, in their proposed modification (l), Defendants request the authority to rely upon all relevant information, not just the enrollees' medical records, in determining TennCare coverage of medical services and in considering and deciding medical appeals. Further, Defendants wish to delete Paragraph C(7) of the 2003 Consent Decree. Defendants contend that Paragraph C(7) of the 2003 Consent Decree confines the information the State may rely upon at a hearing to an enrollee's medical records. Defendants unnecessarily narrow Paragraph C(7)(b), which provides:

> The decisions or opinions of a TennCare beneficiary's treating physician or other prescribing clinician shall not be overruled by either the MCC initially or the state defendants upon review, unless there is substantial and material medical evidence, documented in the beneficiary's medical records, to justify such action. Reliance upon insurance industry guidelines or utilization control criteria of general application, without consideration of the individual enrollee's medical history, does not satisfy this requirement and cannot be relied upon to support an adverse action affecting TennCare services.

(Doc. No. 908 ¶ C(7)(b), at 15-16 (emphasis added); see also Doc. No. 908 ¶ C(4), at 13 (prohibiting the use of utilization control guidelines or other quantitative coverage limits unless supported by an individualized determination of medical necessity based upon the needs of each TennCare beneficiary and his or her medical history).) Pursuant to Paragraph C(7)(b) and consistent with its proposed modification (l), the State may rely on all relevant information as long as the State does so in the context of the individual enrollee's medical history.

Defendants, however, contend that in practice Paragraph C(7)(b) encourages providers to not send medical records to the MCC or State for consideration during an appeal. Without the enrollees medical records, MCCs and the State cannot deny care because Paragraphs C(7)(b) and C(4) require individualized determinations. While there was some evidence that providers may not be sending medical records in a timely fashion in expedited appeals, the record lacks evidence to support

Defendants' allegation that providers fail to send medical records as a result of Paragraph C(7)(b). (See Doc. No. 1182, Tr. at 1925-26; Doc. No. 1231, Tr. at 2366-67; Doc. No. 1202, Tr. at 2584-86.) Although the Court finds that it is necessary to increase the time required to obtain medical records in expedited appeals, see infra pp. 95-96, that does not warrant revising Paragraph C(7)(b). Further, improving provider compliance requires increased enforcement of the rule through penalties, incentives or other methods, but does not necessitate a rule change. Indeed, the State is already considering imposing penalties to increase compliance with this requirement. (See Def. Ex. 210 § 1200-13-16-.06(4)(e), at 12 (draft of medical necessity rules stating that "[p]roviders who violate the requirements of this sub-section shall not seek payment for the services . . . .").) Moreover, providers are required by the law and professional responsibility to follow TennCare's rules and regulations, and because they are subcontractors of the State, their failure to do so is attributable to the State. In any event, what is the alternative – that the State deny appeals without taking into consideration the enrollee's medical history? Both parties agreed that this would be improper. (See Doc. No. 1174, Tr. at 1219 (Dr. Long stating that medical decision should take into consideration individual circumstances); Pl. Ex. 1196 ¶ 15, at 4 (Plaintiff's expert, Dr. Stephen S. Cha, stating that "[r]igorous application of evidence based medicine must always include the context of patient values and preferences, as well as cost-effectiveness.").)[23]

Second, in their proposed modification (n), Defendants seek to place the burden of proof in all

[23] The Draft of Medical Necessity Rules also provide: "If such documentation is not provided or made readily available to the enrollee's managed care contractor, the State government agency performing the functions of a managed care contractor, or the bureau of TennCare for purposes of making an individualized medical necessity determination, the item or service will not be covered." (Def. Ex. 210 § 1200-13-16-.06(4)(e).) This appears to be inconsistent with the 2003 Consent Decree, as revised by this Court's ruling. The rules are in draft form, however, and are not ripe for this Court's determination.

medical appeals upon the enrollee. Defendants contend that the first sentence of Paragraph C(7)(b) effectively places the "burden of proof" on the State to demonstrate why a prescribed drug or service is not justified, rather than requiring a prescriber to justify why the ordered service ought to be granted. Furthermore, Defendants contend that their burden of proof is heightened by the fact that the only evidence they may use to demonstrate why a prescribed drug or service is not justified must be from the beneficiary's medical records. Defendants assert that it is impossible to meet this heightened burden of proof because providers do not produce the medical records in a timely manner and because Defendants are precluded from using medical guidelines that are not in the medical records. Defendants argue that other state's Medicaid programs, commercial plans in Tennessee, and federal regulations place the onus on the prescribing physician to demonstrate the medical necessity of the prescribed treatment.

As a threshold matter, Paragraph C(7)(b) does not allocate which party generally has the "burden of proof" in a medical appeal. Rather, that is governed by Tennessee administrative law, which places the "burden of proof" on the petitioner. Tenn. Comp. R. & Regs. 1360-4-1-.02(3). The petitioner in most appeals for denial of TennCare services is the enrollee. In some cases, the burden of proof can be "assigned to the party who seeks to change the present state of affairs with regard to any issue." Tenn. Comp. R. & Regs. 1360-4-1-.02(7). See Jones v. Bureau of TennCare, 94 S.W.3d 495, 499, 502 (Tenn. Ct. App. 2002) (finding that the TennCare Bureau had the burden of proof because it sought to "change the present state of affairs" by determining that it was no longer medically necessary to provide home health services to an enrollee). As a result, the "burden of proof" in all medical appeals is generally already on the enrollees.

What Defendants seek to change in their proposed modification (n) is not the "burden of

proof" generally, but the burden of proving the medical necessity of a service in cases involving "clinical judgment." Furthermore, the Defendants do not seek to place the burden of justifying medical necessity on the enrollee, but instead seek to place such burden on the provider. The first sentence of Paragraph C(7)(b) states that "decisions or opinions of a TennCare beneficiary's treating physician . . . shall not be overruled . . . unless there is substantial and material medical evidence, documented in the beneficiary's medical records, to justify such action." Therefore, Paragraph C(7)(b) currently presumes that a provider's clinical judgment is correct, and if a provider has decided or believes an enrollee needs a service, such service must be medically necessary.

In order to override this presumption, the State must find "substantial and material evidence" to demonstrate that the service is not medically necessary. "Substantial and material" is defined as "more than a scintilla or mere glimmer." Tenn. Code Ann. § 4-5-322(h)(5). See Wayne County v. Tenn. Solid Waste Disposal Control Bd., 756 S.W.2d 274, 280 (Tenn. Ct. App. 1988). The State must find such evidence from the beneficiary's medical records, but may apply evidence-based guidelines to the facts presented by the enrollee's medical records. (See Doc. No. 908 ¶ C(7)(b), at 15.) The State wishes to remove the presumption in favor of providers by requiring the provider to justify medical necessity at the time the appeal is filed. The Court finds that removal of the presumption is not warranted, but Paragraph C(7)(b) should be revised to make providers explain their decisions when such decisions are unsupported, as well as make it easier to include evidence-based guidelines.

When prescribing care, physicians may not provide a rationale or explain the medical necessity for the care they have provided. Physicians rightly concentrate on providing appropriate medical treatment rather than creating a presentable record for appeal. However, where an appeal is

lodged and the medical records are sparse, the State should not bear the burden of disproving medical necessity.

Furthermore, both parties agree that the appropriate use of evidence-based guidelines – the use of objective clinical evidence to treat specific medical conditions – is beneficial for the patient's health. (Compare Def. Ex. 201 at 4 (Dr. Jacobson opining that "adherence to evidence-based guidelines should be the foundation for medical necessity and is the key to better care and lower cost."), with Pl. Ex. 1196 ¶ 20, at 5 (Dr. Cha opining that the "appropriate use of evidence based medicine can clearly improve the quality of care in this country and should be used for this purpose.").) Thus, Paragraph C(7)(b) should be revised to make it easier to consider evidence-based guidelines.

Accordingly, the Court finds that it is appropriate to revise the first sentence of Paragraph C(7)(b) such that the weight given to the treating physician's opinion shall increase if it is well-supported with evidence from an enrollee's medical records and/or other relevant information. On the one hand, a treating physician's conclusory statements, without more, should not bind the State. On the other hand, the State may not require the treating physician to justify any deviation from the standard course of treatment when the physician's opinion is reasonably supported with evidence from the enrollee's medical records. In making this revision, the Court recommends that the parties consider the standard used to evaluate medical opinions in Social Security disability cases. See 20 C.F.R. § 404.1527(d)(2); see, e.g., Wilson v. Comm'r of Soc. Sec., 378 F.3d 541, 544 (6th Cir. 2004); Buxton v. Halter, 246 F.3d 762, 773 (6th Cir. 2001); King v. Heckler, 742 F.2d 968, 973 (6th Cir. 1984).

Third, in their proposed modification (r), Defendants propose to evaluate all claims for

TennCare services in accordance with the definition of medical necessity established by state law (including regulations issued pursuant to the promulgating statute), and deny any claim for a service that the State has concluded is not medically necessary as that term is defined under state law. Furthermore, Defendants seek to clarify that the State, not a provider, will have the ultimate authority to determine whether a medical item or service that has been prescribed by a provider is medically necessary. Paragraph C(7), as revised by this Court's ruling, and Paragraph C(4) requiring individualized decisions are not inconsistent with the definition of medical necessity recently established by State law, as that definition requires the State to take into consideration the enrollee's medical condition. See Tenn. Code Ann. § 71-5-144(b)(2). Furthermore, the statute does not specify which party has the burden of proving medical necessity. Accordingly, the State may evaluate all claims for TennCare services in accordance with the definition of medical necessity established by State law (including regulations issued pursuant to the promulgating statute), and the State may deny any claim for a service that the State has concluded is not medically necessary as that term is defined under state law.[24] Finally, under the 2003 Consent Decree the State, not a provider, already has the ultimate authority to determine whether a medical item or service that has been prescribed by a provider is medically necessary.

iv. Defendants' Proposed Modification (o) Regarding The State's Right To Appeal Medical Decisions

[24] Plaintiffs also argue that the Tennessee statute defining medical necessity is unreasonable, and disregards the best interests of TennCare enrollees. By the statute's own terms, the definition's details and application are subject to modification through the rulemaking process. Tenn. Code. Ann. § 71-5-144(f). While the State presented a draft of such regulations at the hearing, the language is subject to change prior to promulgation of the authoritative rule. Accordingly, the statute is not ripe for this Court's review.

Paragraph C(13) of the 2003 Consent Decree provides:

> ***When the beneficiary prevails***. If the enrollee prevails at any stage of the appeal process, the decision is binding upon the defendants and their contractors. If the enrollee prevails by decision of an administrative law judge (ALJ), the services shall be provided, and the defendants shall not appeal. An ALJ's decision in an enrollee's appeal shall not be deemed precedent for future appeals. The defendants may apply to this Court for relief from an ALJ's ruling interpreting federal law. The defendants may also enact emergency rules or public necessity rules in accordance with the state Administrative Procedures Act.

(Doc. No. 908 ¶ C(13), at 22.)

The State seeks to modify Paragraph C(13) in order to appeal a medical appeal decision rendered at any stage of the process in favor of the enrollee, consistent with the Tennessee Uniform Administrative Procedures Act. The State contends that this modification is mandated to correct ALJ decisions that are inconsistent with TennCare policies and because Paragraph C(13) is contrary to federal law. Plaintiffs, however, argue that Paragraph C(13) provides significant opportunities to Defendants to prevent ALJ decisions that are contradictory to TennCare policies. For example, ALJ decisions are not deemed precedent for future appeals, Defendants may apply to this Court for relief from an ALJ's ruling interpreting federal law, and Defendants may enact emergency rules or public necessity rules. (Id.)

Notwithstanding the protections available to the State, Paragraph C(13) is contrary to federal law. Federal law, pursuant to CMS' recent clarification, states that when hearing officers are not officials of the single state agency, they cannot issue decisions, policies, or similar actions that are binding on the single state agency. (Def. Ex. 353); see also 42 C.F.R. 431.10(e)(3).[25] CMS' recent

[25] Section 431.10(e)(3) provides:

(e) Authority of the single State agency. In order for an agency to qualify as the

interpretation is not arbitrary or capricious, and represents a change in law that requires modification of Paragraph C(13). See supra Part II.B.2.i. The State's proposed modification (o) is an attempt to conform Paragraph C(13) to federal law. As a result, it is suitably tailored to the circumstances and the State may appeal a medical appeal decision rendered at any stage of the process in favor of the enrollee when such decision is made by a hearing officer that is not an official of TennCare. Paragraph C(13) is still applicable, however, when a decision in favor of the enrollee is made by an official of TennCare.

Furthermore, the State's right to appeal is limited by 42 C.F.R. § 431.246, which provides that TennCare must promptly make corrective payments if (a) the hearing decision is favorable to the applicant or recipient; or (b) TennCare decides in the applicant's or recipient's favor before the hearing. Section 431.246(a) does not distinguish between a hearing decision made by a non-TennCare official and a TennCare official. Rather, it requires prompt corrective action after any hearing decision. Thus, the State must comply with 42 C.F.R. § 431.246 requiring prompt corrective action in the event of a decision favorable to the enrollee at any stage of the appeals process and the State may not await the conclusion of its appeal in order to take corrective action. The State's right to appeal a decision in favor of the enrollee is a right that should be exercised judiciously to target egregious cases and create a uniform policy. As the majority of cases need not be scrutinized for such purposes, the time for corrective action need not be extended. Accordingly, the requirement in

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Medicaid agency--

(3) If other State or local agencies or offices perform services for the Medicaid agency, they must not have the authority to change or disapprove any administrative decision of that agency, or otherwise substitute their judgment for that of the Medicaid agency with respect to the application of policies, rules, and regulations issued by the Medicaid agency.

Paragraph C(16)(c) to take corrective action within five days of a decision in favor of an enrollee need not be modified.[26]

v. Defendants' Proposed Modification (p) Regarding Time Limitations For Filing And Resolving Medical Appeals

In its proposed modification (p), the State requests authority to revise Paragraph C(16) of the 2003 Consent Decree regarding the time limitations for filing and resolving medical appeals to conform with federal requirements. Paragraph C(16) provides a detailed time-line for resolving medical appeals, including expedited appeals, and the penalty for missing a deadline is the resolution of the appeal in favor of the TennCare beneficiary. (See Doc. No. 908 ¶ C(16), at 27-31.) In particular, Defendants must ensure that the MCCs complete reconsideration of the appeals within fourteen days of notification, in the case of standard appeals, or within five days, in the case of expedited appeals. (Id. ¶ C(16)(b), at 28.) Furthermore, standard appeals must be resolved within ninety days and an expedited appeal must be resolved within thirty-one days. (Id. ¶ C(16)(f), at 29.) The State's proposed modification appears to seek to change all the timing requirements of Paragraph C(16), however, on a closer reading of the State's arguments, it only wishes to change two timing

[26] Defendants may further be limited by the timing requirements of 42 C.F.R. 432.244(f), requiring the state agency to take final administrative action within ninety days. As the single state agency, TennCare cannot be bound by decisions, policies, or similar actions of hearing officers that are not officials of TennCare. Therefore, it appears to the Court that final administrative action may not occur until TennCare accepts the non-TennCare hearing officer's decision or the conclusion of any appeal of a non-TennCare hearing officer's decision. See Gomolisky v. Davis, 716 N.E.2d. 970 (Ind. Ct. App. 1999); Shifflett v. Kozlowski, 843 F. Supp. 133, 134-137 (W.D. Va. 1994); cf. Egan v. Davis, 118 F.3d 1148, 1150-51 (7th Cir. 1997). The Court cannot, however, determine whether the procedures Defendants will enact to appeal non-TennCare hearing officer's decisions will meet the ninety-day requirement because such procedures were not articulated to the Court.

requirements. First, the State is concerned with when an appeal is considered "filed" for purposes of starting the ninety- or thirty-one-day clock. Second, the State is concerned with the timing for expedited appeals.

The State argues that the 2003 Consent Decree requirement that the State treat appeals as filed upon the date of receipt instead of the date all information necessary to the appeal is obtained, creates substantial difficulties for the State. (Id. ¶ C(16)(f), at 29.) The State's request, however, ignores the plain language of federal regulations, which requires final administrative action within ninety days of the date the enrollee files an appeal, in the case of standard appeals, or as expeditiously as the enrollee's health condition requires, but no later than three days after receiving a request for an appeal directly from an enrollee or the case file from an MCC, in the case of expedited appeals. See 42 C.F.R. § 431.244(f). Thus, the federal regulations do not make a distinction between the date of receipt of an appeal as opposed to the date all information is gathered.[27]

With regard to expedited appeals, the State finds the five-day requirement for MCC reconsiderations to be most onerous. The State maintains that it is difficult for MCCs to gather medical records, make a determination as to whether a service should be covered, and to respond to the enrollee and the State within five days. The State cites to Plaintiffs' medical witnesses who admitted that they are not able to respond to requests for medical records within the time frames governing expedited appeals. (See Doc. No. 1182, Tr. at 1925-26; Doc. No. 1231, Tr. at 2366-67; Doc. No. 1202, Tr. at 2584-86.) The State also contends that other time-lines in the thirty-one-day period for resolving expedited appeals are unduly burdensome, especially in light of the flexibility

[27] The State does not raise any other significant complaints regarding standard appeals. Moreover, the Court finds that Paragraph C(16) is consistent with federal regulations mandating standard appeals to be resolved within ninety days.

provided by federal regulations.

In the case of expedited appeals federal regulations do not provide a specific number of days within which an appeal need be resolved. To begin with, the State, MCC or provider must decide whether an appeal meets the criteria for expedited resolution defined in 42 C.F.R. § 438.410(a) as "taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function." See also 42 C.F.R. § 431.244(f)(2)-(3). In the context of managed care, federal regulations require MCCs to "establish and maintain an expedited review process for appeals," without specifying a time frame within which the appeal must be resolved. 42 C.F.R. § 438.210(a). In the event the MCC denies the appeal, does not timely resolve it within the process it has created, or the enrollee appeals directly to the state agency, then, the "agency must take final administrative action . . . [a]s expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the [MCC], the case file and information for any appeal . . . [or] from an . . . enrollee, a fair hearing request . . . ." 42 C.F.R. § 431.244(f)(2)-(3). Thus, federal regulations give managed care contractors considerable flexibility in determining expedited appeals, but the State must decide an expedited appeal within three days of receipt. In the past, this flexibility has been abused leading to the more stalwart provisions of the 2003 Consent Decree on timeliness in the appeals process. (See Doc. No. 868 at 11-12.)

The State has not shown that the 2003 Consent Decree's overall thirty-one-day time-line for expedited appeals is unreasonable or unduly burdensome, nor has the State provided an alternative time-line that is suitably tailored to circumstances. Indeed, the Court is concerned that a process for

expedited appeals that greatly exceeds thirty-one days may not comply with federal regulations.[28]

The State has, however, demonstrated that the five-day period for MCCs to gather medical records, make a determination whether the service is covered and respond to the enrollee is unrealistic and unduly burdensome, resulting in coverage of service that may not be medically necessary or even covered under TennCare. Furthermore, federal regulations provide MCCs considerable flexibility in determining expedited appeals and suggest that an administrative action may not be taken until the case file and relevant information is received from the MCC. See 42 C.F.R. § 431.244(f)(2) (stating that action must be taken expeditiously, but no later than three working days after receiving the case file and information from the MCC). Therefore, the Court finds that providers and MCCs should have more time to gather relevant records in expedited appeals. While this additional time to gather records may extend the overall thirty-one-day limit for completing expedited appeals, an extension that greatly exceeds that limit may violate federal regulations, and undermine the purpose of expedited appeals.

In addition, in its proposed modification (p), the State seeks to limit the definition of expedited appeals in Paragraph B(14) to circumstances as required by federal regulations. Paragraph C(16) requires expeditious resolution of an appeal that involves time-sensitive care and Paragraph

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[28] As it is, there appears to be an inconsistency between the federal regulations, which require final administrative action within three days of receipt of the file from an MCC or request from an enrollee, and the 2003 Consent Decree, which requires resolution of an expedited appeal within thirty-one days. This inconsistency is permissible because the 2003 Consent Decree expands the federal definition of an "expedited" appeal, which has led to more expedited appeals than would occur under the federal regulations. (Doc. No. 1188, Tr. at 2097-99.) In order for the State to adequately resolve these additional appeals, more time is required. In addition, the federal regulations give MCCs considerable flexibility, while the 2003 Consent Decree does not. It would be unduly burdensome to deprive both the MCCs and the State of the flexibility permitted in the federal regulations.

B(14) defines time-sensitive care as:

> care which requires a prompt medical response in light of the beneficiary's condition and the urgency of her need, as defined by a prudent lay person; provided, however, that a case may be treated as non-time-sensitive upon the written certification of the beneficiary's treating physician.

(Doc. No. 908 ¶ B(14), at 6.) This is an expansion of federal regulations, which require expeditious resolution in a situation in which "taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function." 42 C.F.R. § 438.410(a). Furthermore, federal regulations do not permit an enrollee or "prudent lay person" to decide whether a situation is in need of expeditious resolution; instead, this decision is left to the State, MCC or provider. See id.; 42 C.F.R. § 431.244(f)(3).

The State argues that this expansion of the federal rules has resulted in the great majority of all appeals being filed as expedited appeals even when there is no urgent medical justification. (See Doc. No. 1279, Tr. at 2053-54; Def. Ex. 351.) The State demonstrated that, excluding pharmacy appeals, from April 2004 to April 2005, expedited appeals are increasing in both aggregate number and in relation to the number of non-expedited appeals. (Id.) Thus, in April 2005, 71.1% of appeals, excluding pharmacy, were expedited appeals. (Id.) The State blames this increase primarily on two factors.

First, the State complains that the definition of "time-sensitive care" in Paragraph B(14) is inappropriate. However, the State's complaints center around the medical appeal form, rather than the actual standard of time-sensitive care. The medical appeal form asks an enrollee if "a fast appeal [is] needed because the care is needed right away?" (Def. Ex. 240) (emphasis added). Furthermore, the instructions inform the enrollee to "[t]ell us if you need a quick decision about this case." (Id.)

(emphasis added). Although these questions are an attempt to simplify the appeals form, they are in no way grounded in the enrollee's medical condition and the urgency of the situation, as the definition of time-sensitive care in Paragraph B(14) requires. Instead, they lead an enrollee to ask if he or she wants a "slow" appeal. (See Doc. No. 1189, Tr. at 1969-70.) Therefore, the State may revise the appeals form to reflect the definition of time-sensitive care in Paragraph B(14). For example, asking whether the enrollee faces an "emergency" is simple and embodies the requirements of Paragraph B(14). Furthermore, the Court recommends that the State include in its instructions to the appeals form examples of time-sensitive care and non-time-sensitive care to further guide the enrollee. The Court also recommends that the State develop guidelines to identify situations that require time-sensitive care to further assist enrollees, providers, and the State.[29]

Second, the State complains that the fact that a "prudent lay person" may determine what is time-sensitive care permits enrollees to file expedited appeals even when their care is not time-sensitive. Although Paragraph B(14) permits the State to treat a case as non-time-sensitive upon the written certification of the beneficiary's treating physician, the State finds that its ability to do so is wholly illusory in practice. The State argues that this is because providers are unwilling to affirmatively oppose expedition at the expense of their patients' wishes and their own desire for prompt reimbursement. (See Doc. No. 1189, Tr. at 1968-69; Doc. No. 1279, Tr. at 2036-39; Def. Ex. 200 at 7 (Defendants' expert, Dr. John Gore, stating that "Providers have no incentive to take the time

[29] The State explained to the Court that it was discouraged by Plaintiffs from developing such guidelines. (Doc. No. 1279, Tr. at 2042-43.) The evidence presented to the Court suggests otherwise. In the past Plaintiffs have consistently supported creating such guidelines (see Def. Ex. 699 at 1, 26, 38), and have reiterated such support as recently as August 2005 (see Doc. No. 1250 at 9). The Court has been disappointed by the parties' inability to cooperate to reach appropriate solutions. This is a prime example in which cooperation could have led to a productive solution to streamline the expedited appeals process.

for such a certification; indeed, even without any clinical considerations, the incentive is to allow for an expedited appeal because the provider's service will be reimbursed all the more quickly.").) The State argues that instead of placing the burden on the State to obtain certification that an appeal is not time-sensitive, the burden should be shifted to the enrollee to obtain certification that the appeal is time-sensitive before filing the appeal.

Shifting the burden to enrollees, however, does not change provider incentives. Providers still have the same incentive not to affirmatively oppose their clients and to receive prompt reimbursement. Shifting the burden to enrollees simply makes it harder for the enrollee to file an expedited appeal. In contrast, the State does not face an unduly high burden in requesting such certification from providers. Indeed, the State could request the certification at the same time it requests the medical records from the providers. Furthermore, the State can require the providers to make such certification under penalty of perjury. Even without such penalty, professional responsibility requires providers to give a certification consistent with the medical condition of the enrollee and not pursuant to "incentives" they may have to receive prompt reimbursement and maintain client relationships. While the Court understands that these are strong incentives, the Court simply cannot accept the State's proposition that TennCare providers abandon professional responsibility for the sake of these incentives. To be clear, Paragraph B(14) does not make responses to requests for certification optional; when the State requests certification, the provider must respond based on his or her medical opinion.[30] Accordingly, the State's request is not suitably tailored to the

[30] The evidence at trial was unclear on this point, but it appears to the Court that the State does not request such certifications. (Compare Def. Ex. 251 (flow chart showing appeals process, which does not indicate that State requests certification), with Def. Ex. 242 (showing request for certification in orthodontia cases); see also Def. Ex. 38 at 30 (McKinsey report finding that the State is unable to consistently satisfy the physician waiver requirement

situation and the Court sees no reason, and the State has not provided any, to limit enrollees' due process rights simply to reduce the State's administrative burden.

vi. Defendants' Proposed Modification (q) Regarding Defective Notices

In its proposed modification (q), the State requests the authority to remedy any defect in a required notice, statement of reasons, or legal authorities by providing a corrected notice or statement, provided that, when the State does so, the time permitted for an enrollee's response will be restarted. The State also requests that Paragraph C(1)(f) and C(1)(g) of the Revised Consent Decree (Modified) be deleted.

Federal regulations specify the content of a required notice, but do not provide a penalty for a defective notice. See 42 C.F.R. § 431.210. Paragraph C(1)(f) of the 2003 Consent Decree binds the State to a defective notice or requires the disputed service to be provided if the notice is not sufficient to support the proposed action. (Doc. No. 908 ¶ C(1)(f), at 9.) The Court previously found that the 2000 Consent Decree was designed to correct systemic problems in the TennCare appeals process, and the strict default rules were implemented to discourage defective notices. (See Doc. No. 868 at 16.) Importantly, the Court held that

> "[f]undamental due process requires that a person be informed in advance of the issues to be addressed at a hearing, so that he or she can be prepared to present evidence and arguments that address those issues," and switching issues from those stated in the notice violates this basic principle. Ortiz v. Eichler, 616 F. Supp. 1046, 1063 (D. Del. 1985); see also Goldberg v. Kelly, 397 U.S. 254, 267-268 (1970) (due process requires that a recipient have timely and adequate notice detailing the reasons for a proposed termination, and an effective opportunity to defend). The "practice of

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effectively).)

> basing decisions on issues raised for the first time at the hearing violates the claimant's procedural rights, specifically the right to receive notice and to refute arguments presented by the agency." Ortiz, 616 F. Supp. at 1063.

(Id. at 17.)

The State has established strict procedures for resolving appeals and complying with the 2003 Consent Decree. (See Def. Exs. 241-42, 250-52, 271; see generally Doc. Nos. 1188-90, 1279.) Accordingly, the State has taken steps to comply with the 2003 Consent Decree and improve the systemic problems in the TennCare appeals process. Further, there are bound to be administrative errors in a system that handles more than 40,000 appeals a year. (See Pl. Ex. 1203.) In light of the steps the State has taken to improve the appeals process, coupled with the fiscal crisis the State is facing, the Court finds that it is appropriate to relax the requirements regarding defective notices. Accordingly, the State or its contractors may remedy any defect in a required notice or statement of reasons or legal authorities by providing a corrected notice or statement, provided that, when the State does so, the time permitted for an enrollee's response will be restarted. Once the State or its contractors has issued a revised notice or statement of reasons or legal authorities, it shall be bound by that notice and may not issue a third revised notice. To do so would be to permit the State and its contractors to revert to the practices this Court previously found impermissible. In addition, the State may not remedy a defective notice at a later stage in the appeals process because this risks delaying the appeals process in violation of 42 C.F.R. § 431.244(f) and would deprive TennCare enrollees of fundamental due process rights. See Ortiz v. Eichler, 616 F. Supp. 1046, 1063 (D. Del. 1985); see also Goldberg v. Kelly, 397 U.S. 254, 267-268 (1970). This ruling also extends to remedying missed appeals deadlines, and Paragraphs C(1)(f)-(g) may be revised to reflect this ruling.

vii. Defendants' Proposed Modification (s) Regarding MCC Change Requests

Finally, in an attempt to limit the largest category of appeals, MCC change requests, the State wishes to implement a reasonable set of geographic and/or clinical hardship criteria to determine when enrollees will be allowed to transfer between MCCs outside of defined open enrollment periods. Neither federal law nor the 2003 Consent Decree prohibit implementing such criteria. As MCC change requests represent the largest category of appeals (see Pl. Ex. 1203), the Court finds that implementing open enrollment periods and imposing reasonable limitations for changing MCCs outside of such enrollment periods is appropriate.

3. Defendants' Proposed Modification (a) Regarding Reforms Approved By CMS

In their proposed modification (a), Defendants request implementation of all reforms approved by CMS, including, but not limited to, those approved in the letters to the State dated March 24, 2005, and June 8, 2005. Pursuant to Rule 60(b) of the Federal Rules of Civil Procedure and the governing case law, the Court cannot revise the 2003 Consent Decree unless the proposed modifications are suitably tailored to the circumstances. See Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367, 391 (1992). Similarly, the proposed modifications must fall within constitutional requirements, as well as federal statutes and regulations. Id. The Court cannot conduct this analysis on future reforms that the State has not yet articulated to this Court. Accordingly, the State may implement the reforms already approved by CMS in its letters to the State dated March 24, 2005 and June 8, 2005, which are consistent with this Court's ruling. The Defendants may not, however, implement future reforms that have yet to be approved by CMS without Court approval, unless such

changes are not inconsistent with the 2003 Consent Decree, as revised by this Court's ruling. This ruling does not alter the requirements of section D of the 2003 Consent Decree, requiring certain monitoring, reporting, and disclosure actions by the State, including 30 days notice to Plaintiffs' counsel of new policies.

4. Defendants' Proposed Modification (t) Regarding Termination Of The 2003 Consent Decree

Finally, in its proposed modification (t), the State requests that the 2003 Consent Decree should terminate in 2007 at the end of the current term of the State's TennCare waiver unless the Court determines that there are ongoing or imminently likely violations of federal law, in which case the decree will be limited to those provisions that are necessary to remedy any such violations of federal law.

The specific terms of a consent decree govern its termination. See Youngblood v. Dalzell, 925 F.2d 954, 961 (6th Cir. 1991). Absent a specific termination clause, the Sixth Circuit identified the following factors a court must consider in determining whether to terminate a consent decree:

> (1) any specific terms providing for continued supervision and jurisdiction over the consent decree; (2) the consent decree's underlying goals; (3) whether there has been compliance with prior court orders; (4) whether defendants made a good faith effort to comply; (5) the length of time the consent decree has been in effect; and (6) the continuing efficacy of the consent decree's enforcement. See Bd. of Educ. v. Dowell, 498 U.S. 237 (1991); Youngblood, 925 F.2d at 960-61. Court supervision is often expected to continue for several years, in order to assure compliance with the relevant decrees. Plyler v. Evatt, 924 F.2d 1321, 1329-30 (4th Cir.1991). When the defendants are shown to be in compliance with its terms, . . . the objectives of the consent decree have been achieved, the district court's jurisdiction over the case may be terminated. Youngblood, 925 F.2d at 957-58.

Heath v. DeCourcy, 992 F.2d 630, 633 (6th Cir. 1993).

The 2003 Consent Decree does not include a specific termination provision. Accordingly, the Court evaluates whether the remaining Heath factors apply. First, the underlying goals of the Decree are to ensure compliance with federal regulations and to "adequately protect the due process rights of plaintiff class members in the context of managed care. . . . The . . . parties recognize that, in doing so, they have, with respect to certain provisions, expanded or otherwise adapted the protections afforded by 42 C.F.R. Part 431, Subpart E . . . ." (Doc. No. 908 at 2.) Although the Court has granted many of Defendants requests for modification, it has denied or limited certain requests relating to the appeals process in order to adequately protect the due process rights of TennCare enrollees. Without these protections, this Court is concerned that the rights of the plaintiff class may be severely restricted. As a result, the necessity of the underlying goal of the Decree has in no way diminished.

Second, the history of this case shows that Defendants and their contractors have not always successfully complied with this Court's orders. Indeed, the 2000 Consent Decree strengthened minimum federal requirements because there was "widespread noncompliance with the 1996 Agreed Order and the federal regulations." (Doc. No. 868 at 12; see also id. at 9-11.) Third, while the Court has noted some evidence of good faith compliance with the 2003 Consent Decree, see supra p. 100, Defendants did not provide sufficient evidence of good faith compliance to support termination of the decree.

Fourth, Defendants contend that because this case is twenty-six years old, and the Consent Decree has been repeatedly rewritten, the time has long since past to end the case.

While the case has been on-going for twenty-six years, the 2003 Consent Decree, which contains the strongest due process protections, has only been in place for two years. Even accepting the Defendants' argument that most of the provisions of the Decree were negotiated in 2000, the version of the decree containing the most robust due process rights for Plaintiffs has only been in existence for five years. This Decree, therefore, is still in its youth. Most importantly, the fact that the 2003 Consent Decree contains the healthiest due process protections, and is the version that has garnered the most good faith compliance, demonstrates that its protections have been crucial and effective. In light of the fiscal problems the State is facing, the temptation to reduce these protections is strong, as has been demonstrated by the present litigation. The Court finds that the protections afforded by the Decree are essential in this time of uncertainty and constantly changing fiscal and legal realities.

In sum, Defendants did not demonstrate that the violations of federal law that gave rise to the 2003 Consent Decree have been remedied or that the objects of the 2003 Consent Decree have been attained. See Heath, 992 F.2d at 633; see also Frew, 540 U.S. at 442 (stating that the Court "must exercise its equitable powers to ensure that when the objects of the decree have been attained, responsibility for discharging the State's obligations is returned promptly to the State and its officials."). Furthermore, Defendants cannot now show that in 2007 the State will have remedied the violations of federal law or attained the underlying objects of the Decree. Indeed, the State's historical non-compliance with the Decree indicates otherwise. When the Defendants believe they have successfully remedied the violations of federal law that gave rise to the 2003 Consent Decree and attained the purpose of the Decree, they may move for termination. At the present time, however, this Court's "continuing enforcement and supervision

of the consent decree[is] essential to achieving the [2003 Consent Decree's] purposes and protecting plaintiffs' rights." Heath, 992 F.2d at 634.

III. CONCLUSION

Orders consistent with the findings contained herein GRANTING in part and DENYING in part the State's proposed modifications to the 2003 Consent Decree have been entered at Doc. Nos. 1256, 1261. The Court further ORDERS the parties to this action to submit revisions to the 2003 Consent Decree that are consistent with this Memorandum and this Court's previously issued Orders within ninety days of the date of entry of this Memorandum.

It is so ORDERED.

Entered this the 15th day of November, 2005.

JOHN T. NIXON, SENIOR JUDGE
UNITED STATES DISTRICT COURT